

1 UNITED STATES DISTRICT COURT  
2  
3 FOR THE DISTRICT OF ARIZONA  
4

5 In Re: Bard IVC Filters ) MD-15-02641-PHX-DGC  
6 Products Liability Litigation )  
7 ) Phoenix, Arizona  
8 ) May 17, 2018  
9 Doris Jones, an individual, ) 1:00 p.m.  
10 )  
11 Plaintiff, )  
12 ) CV 16-00782-PHX-DGC  
13 vs. )  
14 )  
15 C.R. Bard, Inc., a New )  
16 Jersey corporation; and Bard )  
17 Peripheral Vascular, Inc., an )  
18 Arizona corporation, )  
19 Defendants. )  
20 )

21 BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

22 REPORTER'S TRANSCRIPT OF PROCEEDINGS  
23 (AMENDED TO INCLUDE EXHIBIT DESCRIPTIONS)  
24 (Jury Trial - Day 3 - P.M. Session)  
25 (Pages 591 through 719, inclusive.)

21 Official Court Reporter:  
22 Laurie A. Adams, RMR, CRR  
23 Sandra Day O'Connor U.S. Courthouse, Suite 312  
24 401 West Washington Street, Spc 43  
25 Phoenix, Arizona 85003-2151  
(602) 322-7256

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1 APPEARANCES:

2 For the Plaintiff:

3 GALLAGHER & KENNEDY PA

By: Mark S. O'Connor, Esq.

4 By: Paul L. Stoller, Esq.

By: Shannon L. Clark, Esq.

5 By: C. Lincoln Combs, Esq.

2575 East Camelback Road, Suite 1100

6 Phoenix, Arizona 85016

7 LOPEZ MCHUGH LLP

BY: Ramon Rossi Lopez, Esq.

8 100 Bayview Circle, Suite 5600

Newport Beach, California 92660

9 HEAVISIDE REED ZAIC

10 By: Julia Reed-Zaic, Esq.

By: Laura Elizabeth Smith, Esq.

11 312 Broadway, Suite 203

Laguna Beach, California 92651

12 For the Defendants:

13 NELSON MULLINS RILEY & SCARBOROUGH LLP

By: Richard B. North, Jr., Esq.

14 By: Elizabeth C. Helm, Esq.

By: James F. Rogers, Esq.

15 201 17th Street NW, Suite 1700

16 Atlanta, Georgia 30363

## I N D E X

WITNESS:

ROB CARR

By Mr. Lopez

DIRECTCROSSREDIRECTRECROSS

594

EXHIBITRECEIVED

755	Document re: G2 Road Show	655
770	Concept POA-Denali	705
1613	Document re: Recovery Filter	
	Detachments	625
1149	Document re: Line Extension to the	
	Simon Nitinol Filter	622
1219	June 2004 HHE	670
1578	Caudal Migration Test Method	
	Development and G2 Filter Resistance	
	Test Report, 11/27/06	690
2248	PAT PowerPoint Presentation entitled "G2	
	Caudal Migration Update," dated 3/2/2006	684
4409	G2 brochure 2	696
4430	Eclipse Vena Cava Filter Brochure	702
4433	Eclipse Vena Cava Filter Patient	
	Questions & Answers	704
4438	G2 Express Vena Cava Filter Brochure	700
4554	Eclipse Vena Cava Filter Concept POA,	
	Revision 2	632

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P R O C E E D I N G S

THE COURT: Counsel, you may continue.

MR. LOPEZ: Plaintiffs will call Mr. Rob Carr.

THE COURT: All right.

THE COURTROOM DEPUTY: Mr. Carr, please come forward.

01:00PM

Raise your right hand, sir.

(The witness was sworn.)

MR. LOPEZ: May I proceed, Your Honor? Thank you.

ROB CARR,

called as a witness herein, having been duly sworn, was

examined and testified as follows:

DIRECT EXAMINATION

BY MR. LOPEZ:

Q. Good afternoon, Mr. Carr. Thank you for being here.

A. Good afternoon.

01:01PM

Q. You are currently employed by Bard?

A. Yes, I am.

Q. And would it be the Bard Peripheral Vascular Division of

C.R. Bard?

A. Yes.

01:01PM

Q. What's your current title or position there?

A. I'm the vice president of international.

Q. What does that mean?

A. It means that I support all of our business outside of the

United States.

01:01PM

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1 Q. When you say support all of your business, is that -- why  
2 don't you just explain to the jury what that means when you say  
3 you support all of your business outside the United States.

4 A. So I literally support all aspects of the business for our  
5 division outside of America, be that physician training, sales  
6 training, supply, some marketing, some R&D technical questions,  
7 so me and my group support that.

01:01PM

8 Q. So I have just not the word "support" before as a -- does  
9 that mean that you work for somebody who gives you direction to  
10 then give support to other people that are in your  
11 international division?

01:02PM

12 A. So the way our business is structured, commercially, those,  
13 let's take China, the people who work in China don't report to  
14 me so I support their commercial side of their business.

15 Q. Okay. So in other words, your position is basically  
16 commercial or marketing at this point?

01:02PM

17 A. No, it's more than that. It's like I described, all of the  
18 above.

19 Q. Do you have any engineering functions currently at Bard  
20 where you are actually doing engineering type of activities?

01:02PM

21 A. Again, only to answer questions or technical things that  
22 someone might have.

23 Q. Okay. Now, is it true that there's probably no one at Bard  
24 that has been more involved in the aspect of Bard IVC filters  
25 than Rob Carr?

01:03PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 A. As a general statement I think that's probably true.

2 Q. And I think you told us a while back that you know more  
3 about Bard IVC filters than anyone else in the company. Is  
4 that true?

5 A. I don't know if I said that. I think others have.

01:03PM

6 Q. Now, in fact, you have had your deposition taken 10, 11, 12  
7 times in this litigation, is that right? Do you remember that?

8 A. I don't know how many. Several.

9 Q. And you know that you have been designated a number of  
10 times by Bard or its lawyers to testify as a person most  
11 knowledgeable or most qualified on a number of Bard IVC filter  
12 related topics. True?

01:03PM

13 A. Yes.

14 Q. You have been designated to be that person most  
15 knowledgeable to discuss risks, complications in sales. True?

01:04PM

16 A. I don't know specifically.

17 Q. Do you want to look at -- do we need to look at your  
18 depositions to remind you about that?

19 A. Yes, please.

20 Q. Well, let me ask you, can we look at 730, then, Exhibit  
21 730? That's the deposition notice. That was -- I'm sorry it's  
22 a deposition taken April 17, 2003. I'm sorry, 2013.

01:04PM

23 Does this refresh your recollection that your  
24 deposition was taken as a person most knowledgeable on that  
25 date? Is there a next page to this? Keep going. That lists

01:05PM

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1 the subject matter. Keep going. There we go.

2 MR. LOPEZ: Can I admit this, Your Honor, and publish  
3 it to the jury as a deposition notice? This is a deposition of  
4 subject matter.

5 MR. NORTH: Objection 402 and 403 and in violation of  
6 the Court's ruling on Motion in Limine./HRO\*P /HROP I don't  
7 think this page is, Your Honor.

01:05PM

8 THE COURT: Sustained.

9 BY MR. LOPEZ:

10 Q. Okay. Mr. Carr, you were designated as a person most  
11 knowledgeable to discuss risks and complications associated  
12 with the Recovery, G2, G2 Express Filters in a deposition taken  
13 April 17, 2013. True?

01:05PM

14 A. I don't know the exact reasons.

15 Q. Look at the screen.

01:05PM

16 A. Oh. Yes.

17 Q. And you were also designated to be a person most  
18 knowledgeable to talk about the sales brochure for G2 filters.  
19 Do you recall that -- it's not on this. Don't look at the  
20 screen -- at another deposition?

01:06PM

21 A. Again, you would have to -- I don't know the specific  
22 reasons.

23 Q. Well, two months ago I asked you this question: Were you  
24 designated as a person most knowledgeable to testify about  
25 Bard's sales brochures for the G2 Filter? Do you remember

01:06PM

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1 that?

2 MR. NORTH: Objection, Your Honor 402.

3 THE COURT: Overruled.

4 THE WITNESS: Not specifically, no.

5 BY MR. LOPEZ:

01:06PM

6 Q. Well, let me ask you, sir, prior to your coming here to  
7 today to testify, did you prepare yourself to testify?

8 A. Yes.

9 Q. I mean, did you prepare yourself to look at your history of  
10 your involvement in giving depositions so you could give the  
11 jury the best testimony that you possibly could today and the  
12 most truthful testimony?

01:06PM

13 A. I didn't read every document, if that's what you are asking  
14 me. But yes, I prepared.

15 Q. And as part of that preparation, you didn't look at any of  
16 the prior depositions that you have given in this litigation?

01:07PM

17 A. I didn't say that.

18 Q. Did you look at the deposition that you took -- I mean that  
19 was taken on October 29, 2014?

20 A. I don't know.

01:07PM

21 Q. And were you a person most knowledgeable at that deposition  
22 on the sales brochure for the G2 Filter?

23 A. I don't know.

24 Q. Let's look at 753, please. That's the deposition taken on  
25 10-29-2014.

01:07PM



—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 MR. LOPEZ: Go to the page that describes the subject  
2 matter for which Mr. Carr was designated as a person most  
3 knowledgeable since he doesn't remember. There we go. Keep  
4 going one more.

5 BY MR. LOPEZ:

01:08PM

6 Q. Sir, this deposition was taken on October 29, 2014, just to  
7 refresh your recollection. Does this help refresh your  
8 recollection about the subject matter for which you were being  
9 deposed on that day?

10 A. Yes. But I don't see those words on this page.

01:08PM

11 Q. Can we go to the exhibit that's attached?

12 Okay. This is the G2 brochure?

13 A. Yes.

14 Q. And you really don't remember that you were designated as a  
15 person to talk about the sales material as they relate to the  
16 Recovery and G2 Filter three years ago?

01:09PM

17 A. As you said, I have been deposed many times.

18 Q. All right. Let's see if you and I can agree on some  
19 things.

20 The Recovery, the G2, the G2 Express, as well as the  
21 Eclipse and any other so-called retrievable device that is  
22 being marketed by Bard should perform as well as permanent  
23 filters. True?

01:09PM

24 A. They perform differently than permanent filters, so not in  
25 every case, no.

01:10PM

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1 Q. But they should perform as well from the patient's safety  
2 standpoint, should they not?

3 A. They must be safe and effective, yes.

4 MR. LOPEZ: Can we go to Mr. Carr's deposition  
5 November 5, 2013, beginning at Page 41, Line 11. I'm sorry.  
6 October 25, 2013, Page 41.

01:10PM

7 BY MR. LOPEZ:

8 Q. Do you have it in front of you, sir?

9 A. Yes.

10 Q. Okay. This must be the wrong deposition. Is this 11-5-13  
11 or 11-25-13?

01:11PM

12 (Discussion off the record.)

13 BY MR. LOPEZ:

14 Q. There we go. Okay. Sir, see the deposition in front of  
15 you, Line 11?

01:12PM

16 A. Yes.

17 Q. You were asked this question: Sir, would you agree that  
18 optional filters, the Recovery, the G2, the G2 Express should  
19 perform as well as permanent filters? And your answer was yes.  
20 Do you see that?

01:12PM

21 A. Yes.

22 Q. Now we go to 41, same deposition, 41:19, I'm going to ask  
23 you the same question. The Recovery era, the G2 era and the G2  
24 Express, did Bard have a truly permanent filter that was  
25 commercially available? And your answer is: All of them are

01:12PM

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1 truly permanent. Right?

2 A. Yes.

3 Q. So when we talk about Bard retrievable filters, they are  
4 permanent filters?

5 A. Some are only permanent and some are optionally removed. 01:13PM

6 Q. Right. But as a permanent filter, they should be as safe  
7 and effective as any other permanent filter on the market, in  
8 particular, its predicate device the Simon Nitinol Filter.

9 True?

10 A. No. Different filters have different advantages and  
11 disadvantages so not as -- they should all be safe and  
12 effective. 01:13PM

13 Q. Let me ask you, shouldn't the Bard filters perform at least  
14 as well from a safety and effectiveness standpoint and as the  
15 Simon Nitinol Filter? 01:13PM

16 A. They should all meet their specification which shows that  
17 they are both safe and effective.

18 Q. Can we go to Page 44, Line 14 of the same deposition.

19 Sir, you were asked: So shouldn't the G2 still  
20 perform as well as the Simon Nitinol Filter? On that day you  
21 gave me a simple answer which was yes. True? 01:13PM

22 A. Yes.

23 Q. Now, you don't sacrifice safety when you design a filter to  
24 have a retrievable option, do you?

25 A. No. Again, all of our devices are both safe and effective. 01:14PM

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1 Q. I didn't ask you that question. I asked you -- Mr. North,  
2 in his opening statement, seemed to indicate that it was a  
3 little bit more difficult to design an optional filter. You  
4 had to make some compromises. Would you agree that you don't  
5 make compromises to make a device retrievable in the area of  
6 safety?

01:14PM

7 A. No. Again, they are all safe and effective.

8 Q. Would you agree that stability and integrity of the filter  
9 should not be different whether or not it's being implanted in  
10 a patient to be there permanently or potentially to be removed  
11 later?

01:14PM

12 A. I'm sorry. Could you say that again?

13 Q. Well, you know what the word stability means as relates to  
14 an IVC filter?

15 A. Stability? Yes.

01:15PM

16 Q. In fact, it's on one of your brochures. You brag about how  
17 the G2 has taken stability to a new level, correct?

18 A. First of all, we don't brag about anything.

19 Q. Well, stability is an important word when it comes to the  
20 safety of IVC filters. You would agree with me, wouldn't you?

01:15PM

21 A. I would.

22 Q. And integrity, do you know what integrity means as it  
23 relates to a filter?

24 A. I do.

25 Q. What does integrity mean?

01:15PM

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1 A. It means that it stays together.

2 Q. So it shouldn't break and should stay where you put it.

3 That's the purpose. That's the idea in designing an IVC

4 filter. Correct?

5 A. That is the goal, yes.

01:15PM

6 Q. And that stability, that integrity, should not be different

7 whether or not the device is being implanted to stay in

8 permanently or implanted to potentially be taken out later.

9 True?

10 A. Again, they are all --

01:15PM

11 Q. Sir, is that true or not?

12 A. No, it's not.

13 Q. So they can have different stability and integrities

14 depending upon whether or not it's left in permanently or comes

15 out, say, sometime after it's implanted? Is that what you are

01:16PM

16 telling the jury?

17 A. Yes. I'm saying that they have different performance

18 specifications that all show that they are both safe and

19 effective.

20 Q. So when you were selling the Eclipse Filter, the G2 Filter,

01:16PM

21 the Recovery Filter, were you telling doctors that if you are

22 going to leave this in permanently it has a different safety

23 profile than if you take it out after a certain period of time?

24 Yes or no?

25 A. No.

01:16PM

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1 Q. You were telling them that the G2, the Eclipse would  
2 perform safely and effectively whether or not you were putting  
3 it in short-term or whether or not you were going to leave it  
4 in for the life of the patient. True?

5 A. Yes, and it does.

01:16PM

6 Q. Other than the Asch pilot study that we heard some  
7 testimony about yesterday for retrievability of the Recovery  
8 Filter, and the EVEREST trial for retrievability of the G2  
9 Filter, there has been no Recovery, G2, G2X, G2 Express, or  
10 Eclipse Filter that has undergone a controlled clinical trial  
11 where patients are enrolled and monitored. True?

01:17PM

12 A. Other than those two, no.

13 Q. There has never been a long term monitored and controlled  
14 clinical trial of any Bard filter from Recovery to and  
15 including Eclipse specifically designed to determine safe  
16 retrievability beyond 180 days. True?

01:17PM

17 A. Not beyond 180 days. But the time period is very long.

18 Q. And there never been a long term monitored or controlled  
19 clinical trial of any Bard filter, up to and including Eclipse,  
20 specifically to determine long term safety and effectiveness as  
21 a permanent device. True?

01:17PM

22 A. Not past 180 days, no.

23 Q. The Asch study provided data for retrieval in less than 50  
24 patients with an average time to retrieval of 53 days. True?

25 A. I don't know.

01:18PM

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1 Q. You don't know anything about the Asch study?

2 A. I know a lot about the Asch study --

3 Q. Not about that aspect --

4 MR. NORTH: Your Honor, could he allow the witness.

5 THE COURT: Would you please let the witness answer  
6 before you interrupt, Mr. Lopez.

7 MR. LOPEZ: Sorry.

8 THE WITNESS: I know a lot about the Asch study. I  
9 just don't know exact numbers.

10 BY MR. LOPEZ:

11 Q. And EVEREST provided data for retrieval in less than 50  
12 patients with an average time of retrieval of 140 days. True?

13 A. Again, I don't know those numbers, no.

14 Q. Would you agree with -- do you know who Mr. Chris Ganser  
15 is?

16 A. Yes.

17 Q. Who is Mr. Chris Ganser?

18 A. He was a -- I don't know his exact title but he was a head  
19 of quality.

20 Q. He was head of quality at the corporate level at C.R. Bard.  
21 True?

22 A. Yes.

23 Q. He would have been someone that would have had on the  
24 hierarchy a very high position, very close to the president and  
25 CEO. True?

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1 A. I don't know who he reported to, but he worked at the  
2 corporate office.

3 Q. Would you agree with Mr. Ganer if he said that  
4 transparency in matters that affect patients' safety should be  
5 embraced as a primary corporate obligation. Do you agree with  
6 that?

01:19PM

7 A. I do.

8 Q. Now, the ultimate decision about -- would you agree with  
9 this, sir: That the ultimate decision about the acceptability  
10 of inherent risks associated with Bard IVC filter rests with  
11 the patient who is going to receive the filter?

01:19PM

12 A. I don't know that. I think it might be the doctor.

13 Q. You think -- you are not familiar with the informed consent  
14 requirement before one of your medical devices can be implanted  
15 in a patient?

01:19PM

16 A. Yes.

17 Q. You know that ultimately, the person who needs to make the  
18 decision about whether or not to implant something in their  
19 body that's potentially dangerous is the patient?

20 A. I don't know. I think I listen to my doctors, so I'm  
21 not --

01:20PM

22 Q. I know. But the decision, I'm talking about. I mean --

23 A. Yes. They sign a consent.

24 Q. Thank you. Your wife is a doctor, right?

25 A. My wife is an immunologist.

01:20PM



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1 Q. And you know about informed consent, right?

2 A. No, she doesn't practice.

3 Q. When she was practicing she just couldn't treat patients  
4 and give them whatever she wanted to give them. She had to  
5 have an informed consent discussion with them and give her all  
6 the various options of treatment and the patient had to say  
7 yes. True?

01:20PM

8 A. No. My wife never practiced.

9 Q. Okay. But you know that as being married to a doctor that  
10 that's how it works in the real world, that patients are the  
11 ones who have to be informed and be provided with information  
12 so that they can make the decision on whether or not they want  
13 something implanted in their body. Right?

01:20PM

14 A. I know that patients sign consents.

15 Q. And certainly people at Bard, the marketing department, the  
16 sales department, and other departments shouldn't be making  
17 decisions on behalf of people like Doris Jones as to whether or  
18 not the risks of your devices are acceptable to her. True?

01:21PM

19 A. No, I don't believe that.

20 Q. You don't believe what?

01:21PM

21 A. That we don't make those determinations.

22 Q. You shouldn't?

23 THE COURT: Are you saying should or should not?

24 BY MR. LOPEZ:

25 Q. Bard should not be making decisions about acceptability,

01:21PM

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1 about risks that are acceptable to patients like Doris Jones.

2 Do you agree with that?

3 A. No, I don't. I don't understand your question maybe.

4 Q. Maybe you don't.

5 Will you agree with this, sir, that patients are  
6 entitled to receive full disclosure of all material information  
7 that Bard possesses about safety, performance, design  
8 deficiencies, and complications in order to make informed  
9 decisions about whether or not to consent to the insertion of a  
10 Bard IVC filter in their body. Do you agree or disagree with  
11 that?

01:22PM

01:22PM

12 A. I don't think I agree with that fully, no.

13 Q. Sir, do you agree that it is a reasonable expectation of  
14 doctors and patients that they treat that medical device  
15 companies provide honest, accurate, and updated information  
16 about the safety and effectiveness of its potentially dangerous  
17 products to allow doctors to fulfill their obligation of  
18 informed consent to the patient?

01:22PM

19 A. Yes, and we do.

20 Q. In order for a physician caring for patients who are  
21 candidates for IVC filters to provide their patients with  
22 appropriate informed consent, the companies who manufacture,  
23 market, and profit from these devices must provide current and  
24 up-to-date information about the frequency, severity, and type  
25 of complications associated with their specific filter. Do you

01:22PM

01:23PM

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1 agree with that, sir?

2 A. No, I don't.

3 Q. Do you agree that the experiences of other physicians with  
4 the use of potentially dangerous medical devices like IVC  
5 filters, especially new devices, and particularly when there's  
6 no controlled clinical trial that exists that provides data for  
7 long term safety and effectiveness is important information to  
8 share with other doctors?

01:23PM

9 A. But there is clinical trial data.

10 Q. I said long term safety and effectiveness information.

01:23PM

11 A. There is long term safety and effectiveness.

12 Q. And where did you get that?

13 A. From the EVEREST trial.

14 Q. I'm sorry?

15 A. EVEREST trial.

01:23PM

16 Q. The EVEREST trial where you follow a patient for 180 days  
17 and didn't follow them after? That's the long term study that  
18 you did?

19 A. Yes.

20 Q. That's long term?

01:24PM

21 A. Yes.

22 Q. And so that's a study where I think about a third of the  
23 people went on and weren't followed and Bard knows nothing  
24 about what happened to those people and you consider that a  
25 long term safety and effectiveness study. True?

01:24PM

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1 A. Yes. All trials have an end point.

2 Q. I understand. But that study, sir, the purpose of that  
3 study -- and the study was designed to determine whether or not  
4 a G2 Filter can be retrieved within 180 days. True?

5 A. Among other things.

01:24PM

6 Q. But, sir, that part of it was true. Right?

7 A. Yes.

8 Q. It wasn't designed to follow patients after 180 days.  
9 True?

10 A. That's correct.

01:24PM

11 Q. So you know nothing about what happened to patients like  
12 Ms. Jones who had a filter in her for a year, two years, three  
13 years, four years after they received a filter like the G2  
14 Filter. True?

15 A. Unless they came back for a removal.

01:25PM

16 Q. But you didn't ask them to, right, you didn't follow them?

17 A. No. It's the physician's discretion on when a filter gets  
18 removed.

19 Q. Now, I asked you about the experience of other physicians,  
20 and we just heard from Mr. Modra. And one of the primary ways  
21 that Bard finds out about experiences of other physicians is  
22 when physicians voluntarily report adverse events to Bard.  
23 Correct?

01:25PM

24 A. Yes. That's one way.

25 Q. And we know that -- well, let me ask you. Isn't it true

01:25PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 that Bard has never formally initiated a registry to follow  
2 patients among any physician population to see how patients do  
3 after one of your devices is implanted in them?

4 A. I don't think so.

5 Q. And you know what a registry is, right?

01:26PM

6 A. I do.

7 Q. What is a registry?

8 A. A study, if you will, done on product that is already on  
9 the market.

10 Q. That's how you gather clinical data on patients who may  
11 have one of your devices in long term because you didn't have a  
12 long term study for the Eclipse device before you put it on the  
13 market, did you?

01:26PM

14 A. No. I disagree.

15 Q. What was the long term study called that related to the  
16 Eclipse?

01:26PM

17 A. The EVEREST trial.

18 Q. I'm glad you said that. So what we're talking about with  
19 respect to the Eclipse, that the information that was provided  
20 in the EVEREST trial is applicable to the Eclipse Filter.

01:27PM

21 True?

22 A. A lot of it, yes.

23 Q. Sir, would you agree with me that medical device companies  
24 are required to follow federal regulations with or without FDA  
25 enforcement?

01:27PM

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1 A. I don't know what that means, but it is a regulated  
2 industry, yes.

3 Q. What was it you didn't understand when I asked you whether  
4 or not a medical device company was required to follow federal  
5 regulations with or without FDA enforcement?

01:27PM

6 A. I don't know what "with or without FDA enforcement" is.

7 Q. In other words, you have to follow federal regulations  
8 whether or not FDA is knocking on your door and saying follow  
9 this regulation. You have to follow your regulations, right?

10 A. Of course.

01:27PM

11 Q. Mr. Modra -- Mr. O'Connor asked Mr. Modra, FDA doesn't hang  
12 out at Bard, right?

13 A. No, they don't.

14 Q. And there's no one at Bard that hangs out at FDA, right?

15 A. We visit with the FDA often.

01:27PM

16 Q. I'm talking about was there for their everyday activities?

17 A. No.

18 Q. When you send in one of these Med Watch reports that get  
19 into the MAUDE database, you don't know what happens to it when  
20 it gets to the FDA, do you?

01:28PM

21 A. It gets put in the MAUDE database.

22 Q. That's what happens. What else besides that happens? You  
23 don't know, do you?

24 A. I don't know.

25 Q. Sir, would you agree that it's illegal to sell a misbranded

01:28PM

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1 or adulterated medical device?

2 A. I would.

3 Q. And if a company wanted to know whether or not it was  
4 selling a device that was misbranded or adulterated, they just  
5 have to look up in the federal regulations as to what those two  
6 terms or how those two terms are defined. True?

01:28PM

7 A. I don't understand your question. Sorry. Yes. I can look  
8 up terms.

9 Q. I said if a company wanted to know whether or not it was  
10 selling a misbranded or adulterated medical device, they could  
11 look up those terms in federal regulations to see how they are  
12 defined?

01:29PM

13 A. Yes. We could look them up.

14 Q. And if as you look them up, and as they are defined, the  
15 device is misbranded or adulterated, it's misbranded or  
16 adulterated even if the FDA isn't telling you that it is.  
17 True? Is that true or not, sir?

01:29PM

18 A. I guess so. It's a hypothetical question. I don't know.

19 Q. And, sir, would you agree that the safe design of Bard  
20 filters are the exclusive responsibility of Bard and no one  
21 else?

01:29PM

22 A. Yes.

23 Q. If Bard is aware of design deficiencies in any of its IVC  
24 filters, in other words, there's data that suggests and there's  
25 discussions and analysis of your devices that say, you know

01:30PM

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1 what, I think we ought to do something about this design. It  
2 may be increasing the risk of certain complications. You don't  
3 need the FDA to tell you it's defectively designed. It's your  
4 responsibility to know whether or not a device is defectively  
5 designed?

01:30PM

6 A. They are not defectively --

7 Q. Do you agree?

8 A. I do not agree they are defectively designed.

9 Q. I didn't ask you --

10 MR. NORTH: Your Honor, he's arguing with the witness.

01:30PM

11 THE COURT: Excuse me. Mr. Lopez, wait for the  
12 answer. Re-ask the question.

13 MR. LOPEZ: Your Honor, could I just ask the witness  
14 be responsive to my questions?

15 THE COURT: If you want to have him say yes or no,  
16 tell him that.

01:30PM

17 MR. LOPEZ: If okay.

18 THE COURT: If he asks you for a yes or no answer, Mr.  
19 Carr, you can either say yes or no, or you can say I can't  
20 answer that yes or no, in which event he can ask you another  
21 question.

01:30PM

22 THE WITNESS: Thank you.

23 BY MR. LOPEZ:

24 Q. Sir, if the company -- take this as a hypothetical for now.  
25 If Bard determines that it is experiencing increased,

01:31PM



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1 unexpected complications with the design of a filter after it's  
2 been on the market for a short period of time and that they  
3 have determined that the filter needs to be designed  
4 differently, you don't wait for FDA to tell you that to know  
5 that you need to redesign the filter. True? Yes or no?

01:31PM

6 A. Yes, in that hypothetical.

7 Q. I think I have asked you this already, but would you agree  
8 that expectations and acceptability of the risks and benefits  
9 of a Bard IVC filter are exclusively the rights of a doctor and  
10 his or her patient?

01:31PM

11 A. I don't understand that question. I'm sorry.

12 Q. Well, Dr. Ciavarella understood it when I asked him at his  
13 deposition.

14 THE COURT: Excuse me. No more commentary on the  
15 answers. Just ask questions.

01:32PM

16 BY MR. LOPEZ:

17 Q. Sir, would you agree with Dr. Ciavarella -- who is Dr.  
18 Ciavarella?

19 A. He is the head of clinical affairs for Bard.

20 Q. Back at the time of the Eclipse Filter and the G2 Filter,  
21 Recovery Filter, he was the only medical doctor on the team  
22 involved with actual internal, employed by Bard team, he was  
23 the only medical doctor. True?

01:32PM

24 A. Maybe. Yes.

25 Q. Okay. If Dr. Ciavarella testified that expectations and

01:32PM

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1 acceptability of the risks and benefits of a Bard IVC filter  
2 are exclusively the rights of a doctor and his or her patient,  
3 would you agree?

4 A. I don't understand the context. I'm sorry. I'm missing  
5 something. 01:32PM

6 Q. Sir, the information you, meaning Bard, provide doctors  
7 should be what is important to doctors and ultimately to  
8 patients in an informed consent situation about whether or not  
9 they choose a Bard IVC filter, a competitor's filter, or some  
10 other alternative means of treatment or therapy. True? 01:33PM

11 A. Yes.

12 Q. And there is no higher duty that a device company has than  
13 to make sure the doctor has all the risk benefit information he  
14 or she needs to decide whether or not to use the company's  
15 product, a different product, or to seek other alternatives of 01:33PM  
16 treatment for his or her patient.

17 Do you agree with that?

18 A. I don't understand what you mean by "no higher duty." Yes.  
19 We inform physicians.

20 Q. But I'm talking about no higher -- do you think of a higher 01:33PM  
21 duty you have as a medical device manufacturer than what I just  
22 read, and that is to make sure that doctors have all the risk  
23 benefit information they need to determine whether or not to  
24 use your product, a different product, or to seek other  
25 alternatives of treatment for his or her patient? 01:34PM

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1 A. I think all the relevant information, yes.

2 Q. No higher duty. Would you agree with that?

3 A. Of the relevant information, yes.

4 Q. Let's talk a little bit about you and your life with IVC

5 filters. You started that track when you were employed by

01:34PM

6 Nitinol Medical Technologies. True?

7 A. Yes.

8 Q. And tell us a little bit about that.

9 A. Nitinol Medical Technologies was a small company in Boston

10 that was developed by a world famous interventional radiologist

01:34PM

11 named Morris Simon. And we had two primary products that we

12 worked on.

13 One was a device to fix a hole in your heart, and then

14 the other one was a vena cava filter. So the Simon Nitinol

15 Filter, which is the first Nitinol device, which is what our

01:35PM

16 filters are made of in the world was named after him. He was

17 very passionate about vena cava filters. I was fortunate to

18 come there and be one of probably about 15 employees.

19 And so we had the Simon Nitinol Filter and Dr. Simon

20 felt that it was very important to develop a new filter that

01:35PM

21 was removable. So at the time in the world there were no

22 removable filters. So a lot of patients who could and should

23 get filters probably weren't.

24 And so we embarked on a journey to develop that filter

25 which the first one became Recovery, which was sold to Bard at

01:35PM

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1 some point, 2001, and I moved to Bard in 2002.

2 Q. Okay. You came to Bard in 2002 because Bard had acquired  
3 NMT, right?

4 A. I came on my own, but yes.

5 Q. Well, I mean, Bard had acquired the technology of the  
6 Recovery Filter?

01:36PM

7 A. They had, but they chose to hire me.

8 Q. And there was a dispute that went on for about a year  
9 between Bard and NMT about whether or not Bard was going to buy  
10 them or someone else was going to buy that technology. Do you  
11 remember that?

01:36PM

12 A. Yes, before that.

13 Q. And during that year, basically the R&D with respect to the  
14 Recovery Filter had shut down other than the Asch study, I  
15 think, continued. True?

01:36PM

16 A. It didn't shut down. It was completed. The filter was  
17 essentially designed and it was being studied in the Asch  
18 Study.

19 Q. Nothing else was going on other than following what was  
20 going on with Dr. Asch's patients, correct?

01:37PM

21 A. I don't know about nothing else, but no in general.

22 Q. Then were you part of the due diligence team when Bard was  
23 looking at acquiring NMT?

24 A. I was.

25 Q. And isn't it true that one of the compelling reasons why

01:37PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 NMT chose Bard was because of Bard's relationship in the  
2 commercial world with doctors and they had a sales force and  
3 they had ins at hospitals?

4 A. The primary reason was Bard was already selling our Simon  
5 Nitinol Filter. They were already selling the Simon Nitinol  
6 Filter so they were a very logical partner to purchase the  
7 design.

01:37PM

8 Q. Do you recall that they had about 100 sales reps during  
9 that period of time?

10 A. I don't know the number. That sounds high.

01:37PM

11 Q. How about 10 district managers and three regional managers.  
12 Does that sound too high?

13 A. I don't know.

14 Q. Who was the marketing manager at the time?

15 A. At Bard?

01:38PM

16 Q. Yes.

17 A. Paul Stagg, I believe.

18 Q. And someone named Janet Hudnall later became the marketing  
19 manager for the Recovery Filter?

20 A. After it moved to Arizona.

01:38PM

21 Q. Now, you mentioned the Simon Nitinol filter. We have heard  
22 that a few times here. And the Simon Nitinol Filter is only a  
23 permanent filter, correct?

24 A. It was only a permanent filter, yes.

25 Q. Bard stopped selling it, what, about a year ago?

01:38PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 A. 18 months maybe. I don't know.

2 Q. We may talk about that a little bit later.

3 Now, when the Simon Nitinol Filter was being sold by  
4 NMT, and then after it was being sold by Bard -- let me  
5 rephrase that.

01:38PM

6 Actually, Bard was the marketing arm of the Simon  
7 Nitinol Filter even when it was being manufactured by NMT,  
8 correct?

9 A. Yes.

10 Q. And during that period of time, did Bard and NMT have to  
11 follow the same requirements of reporting adverse events to  
12 FDA?

01:39PM

13 A. Yes.

14 Q. In other words, whether or not it was a permanent filter, a  
15 retrievable filter, and whether or not the report went to Bard  
16 or whether or not it went to NMT, there was a requirement to  
17 report that to FDA, right?

01:39PM

18 A. I'm not sure of that, actually.

19 Q. But Bard was able to obtain, before they launched the  
20 Recovery Filter, whatever data that NMT had about the Simon  
21 Nitinol Filter's safety and performance. True?

01:39PM

22 A. Yes.

23 MR. LOPEZ: Okay. Could we see Exhibit 1149, please,  
24 Gay. Show it to the witness for now.

25 BY MR. LOPEZ:

01:40PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. Sir, are you familiar with this document?

2 A. Only from yesterday.

3 Q. You saw it yesterday for the first time?

4 A. Yes.

5 Q. And, sir, if you would look at -- this is a Nitinol Medical 01:40PM

6 Technologies -- do you know what a line extension to the Simon

7 Nitinol Filter refers to?

8 A. Ultimately the Recovery Filter.

9 Q. And if you look at Page 17 of this document, in the first  
10 paragraph, this would have been a document that Bard would have 01:40PM

11 received as part of its due diligence from Nitinol Medical

12 Technologies. True?

13 A. I don't know where Bard got it, but I would assume so.

14 Q. This was about the Trademark Retrievable Filter. Isn't

15 that another name for the Recovery Filter? 01:41PM

16 A. No. It's not another name. There was no name to Recovery

17 Filter when this draft was initiated.

18 Q. My apologies. That is referring to what ultimately became

19 the Recovery Filter. True?

20 A. Yes. 01:41PM

21 Q. Okay. And does this document provide information about the

22 reports of filter fracture, the rate of filter fractures that

23 was available to NMT as of July 1997?

24 A. There's a paragraph in this very early draft document that

25 does say that. But I don't know what this document is. 01:41PM

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1 Q. All right.

2 MR. LOPEZ: Your Honor, I would still like to offer  
3 this into evidence. And I could lay a foundation that it was  
4 produced to us as an NMT document bearing -- this is part of  
5 the due diligence. It bears a Bard Bates stamp number that was  
6 produced to us as a document kept in the ordinary course of  
7 business.

01:41PM

8 MR. NORTH: No objection, Your Honor.

9 THE COURT: 1149 is admitted.

10 MR. LOPEZ: May I publish this to the jury, Your  
11 Honor, please?

01:42PM

12 THE COURT: Yes.

13 BY MR. LOPEZ:

14 Q. Just to give us some perspective, the Simon Nitinol Filter  
15 was the predicate device that allowed the Recovery Filter to be  
16 cleared to be marketed in the United States. Yes or no?

01:42PM

17 A. Yes.

18 Q. And which meant that --

19 THE COURT: Hold on just a minute Mr. Lopez.

20 Check that monitor.

01:42PM

21 THE COURTROOM DEPUTY: Do you mind if they slide over?

22 THE COURT: Go ahead and slide over just two seats.

23 You can go ahead, Mr. Lopez.

24 MR. LOPEZ: Thank you, Your Honor.

25 BY MR. LOPEZ:

01:43PM



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1 Q. As a predicate device, in order to be cleared, it is  
2 required that the Recovery Filter had to be substantially  
3 equivalent to the Simon Nitinol Filter from a safety and  
4 effectiveness standpoint. True.

5 A. As well as the Greenfield Filter.

01:43PM

6 Q. As well as the Greenfield. Both. Not either but both,  
7 right?

8 A. They were both predicate devices.

9 Q. And we heard from Carol Vierling earlier today who  
10 ultimately testified that even the clinical data as it relates  
11 to the Simon Nitinol Filter was important to consider for  
12 substantial equivalence. Do you agree with that?

01:43PM

13 A. I think all of the data is important.

14 Q. Here's the data that Bard had in a 1997 document about  
15 fractures associated with the Simon Nitinol Filter.

01:44PM

16 As of 1997, how long had the Simon Nitinol Filter been  
17 on the market?

18 A. Six years, I believe.

19 Q. Actually, it says that NMT --

20 A. Nine years.

01:44PM

21 Q. Over nine years. What does in vivo experience mean?

22 A. In humans.

23 Q. In people, right?

24 A. Yes.

25 Q. And NMT has reviewed their clinical trial database, their

01:44PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 post-marketing complaint files, and the literature to identify  
2 any fatigue-related issues associated with the SNF. That's the  
3 Simon Nitinol Filter, correct?

4 A. Yes.

5 Q. And there were two reports of asymptomatic filter fracture  
6 identified for a rate of 0.006 percent. Did I read that  
7 correctly?

01:44PM

8 A. You did.

9 Q. Then it cites McCowen 1992. Do you see that reference?

10 A. I do.

01:45PM

11 Q. And NMT has concluded that fatigue of the SNF has not been  
12 a clinical problem. Bard knew that in 1997, right?

13 A. If they read the document, yes.

14 Q. They should have read the document if they were doing their  
15 due diligence, number one; number two, if they were going to  
16 establish substantial equivalence for the SNF they should have  
17 known about this clinical history. Would you agree with me?

01:45PM

18 A. No, I don't agree because this is a very early draft with  
19 very little information in it.

20 MR. LOPEZ: Let's go to Exhibit 1613, please, Gay.

01:45PM

21 Very first page.

22 BY MR. LOPEZ:

23 Q. Sir, who is Cindi Walcott?

24 A. She worked in our quality department.

25 Q. And you heard me talk about Dr. Ciavarella?

01:46PM

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1 A. Yes.

2 Q. And Dr. David Ciavarella was the medical director at Bard,  
3 correct?

4 A. He said he's had various roles.

5 Q. This is regarding Recovery Filter detachments. Do you see  
6 that?

7 A. In the subject, yes.

8 Q. And earlier today Mr. Modra clarified that a detachments  
9 mean fractures. Would you agree with that?

10 A. I would.

11 Q. And does this provide additional information to Bard about  
12 the history of the Simon Nitinol Filter?

13 MR. LOPEZ: Gay, could you call out that second full  
14 paragraph where it says "today."

15 Your Honor, I'd like to offer this Exhibit 1613 into  
16 evidence at this time and ask for --

17 MR. NORTH: No objection. I'm sorry. No objection.

18 THE COURT: Admitted.

19 MR. LOPEZ: May I publish it to the jury?

20 THE COURT: Yes.

21 BY MR. LOPEZ:

22 Q. This is in 2004. This is about seven years later, right?

23 A. Yes.

24 Q. And if Bard was doing their duty in fulfilling their  
25 obligation they would have been tracking the Simon Nitinol

01:46PM

01:46PM

01:46PM

01:47PM

01:47PM

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1 Filter just like they were tracking the Recovery Filter with  
2 respect to complaints from doctors, right?

3 A. Yes.

4 Q. And making sure those got reported to the MAUDE database.  
5 True?

01:47PM

6 A. No.

7 Q. No?

8 A. I don't think everything was reported at that point. The  
9 instructions on what to report have changed over time.

10 Q. In reality, this the data here has nothing to do with  
11 MAUDE. This is data that Bard has. They didn't have to go to  
12 MAUDE to get the information that's contained in this document,  
13 right? This is information that Bard had internally in their  
14 own files. Agreed?

01:47PM

15 A. Yes.

01:48PM

16 Q. In fact, this reads: Today I reviewed all detachments  
17 reports as complaints for our Simon Nitinol vena cava filter,  
18 SNF. Our electronic database goes back to 2000. There were  
19 just two reports of fractures/detachments out off 67,800 global  
20 units sold during this time frame.

01:48PM

21 Did I read that correctly?

22 A. Yes, you did.

23 Q. And this only goes back to 2000, so we don't know what  
24 happened between 1997 and 2000, at least with the documents I  
25 have shown you thus far. Correct?

01:48PM

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1 A. Yes.

2 Q. But we know as of 1997 the complaint -- the fracture rate  
3 was .006?

4 A. We know the reported fracture rate was 006.

5 Q. You don't know what the real rate is because you never did  
6 a study that would follow patients beyond 180 days to see how  
7 many fractures people might have if they had the device in for  
8 one year, two years, five years, 10 years. True?

01:49PM

9 A. Yes. We did not do that study.

10 Q. Thank you. Now, during the entire time that the Simon  
11 Nitinol Filter was on the market, did there ever have to  
12 undergo any design changes?

01:49PM

13 A. Yes.

14 Q. Any design changes that made it more durable to migration  
15 or fractures?

01:49PM

16 A. I don't know about fracture. Not migration.

17 Q. Did you ever have to do a health hazard evaluation with  
18 respect to any adverse events that were being reported to Bard  
19 about the Simon Nitinol Filter?

20 A. No.

01:49PM

21 Q. It was sold internationally, too, wasn't it?

22 A. Yes, but not very many places.

23 Q. Were there any internal discussions within Bard about the  
24 Simon Nitinol Filter that involved any controversies regarding  
25 its design, its safety, or performance?

01:50PM

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1 A. Yes.

2 Q. And when did that happen?

3 A. It happened periodically because the design of the filter,  
4 many people didn't like the design because of how it was  
5 deployed. It deployed into the vessel differently than other  
6 filters. And some would say it was difficult to put in the  
7 right place all the time.

01:50PM

8 Q. Did anyone ever say that 2 out of 67 fractures was too many  
9 fractures and we ought to redesign this thing to take care of  
10 fractures?

01:50PM

11 A. No.

12 Q. In fact, how about migration? There were virtually no  
13 reports of migration with the Simon Nitinol Filter?

14 A. No. That's not true.

15 Q. If I were to look in your database, I mean, in your  
16 tracking and trending of the complaints that Bard received on  
17 migration, would I see anyone who -- well, let me take that  
18 back. I'm talking about adverse events from the field. Do you  
19 understand what I'm saying? Complaints that get reported to  
20 Bard, anybody who had a serious injury that caused them to be  
21 hospitalized by a migration of a Simon Nitinol Filter?

01:50PM

01:51PM

22 A. I think there have been, yes.

23 Q. If there had been it better be in your files. Right?

24 A. Unless it happened before 2000, like you said.

25 Q. And if it's not in your files, you are just making that up.

01:51PM

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1 Wouldn't you agree with me?

2 A. No, I'm not making it up. There's literature. There's  
3 communication. There are many ways that complaints come into  
4 our system.

5 Q. When I look at the tracking and trending there are reports  
6 that Bard does where they list the Simon Nitinol Filter, there  
7 are virtually no migrations reported. We're talking about  
8 single digit migrations, aren't we?

01:51PM

9 A. I don't know. I would have to look at it.

10 Q. You don't know the answer to that question?

01:52PM

11 A. Yes. I don't know the answer to that question.

12 Q. We'll just let that document number speak for itself,  
13 right?

14 A. This document speaks for itself.

15 Q. I'm talking about the tracking and trending that actually  
16 lists the number of migrations and fractures for a Simon  
17 Nitinol Filter. That's the information you would need to know  
18 what that number was. True?

01:52PM

19 A. I don't know what you are talking about. Sorry. Yes, if  
20 there was that document, I would assume it were true.

01:52PM

21 Q. Now, we just heard from Dr. Asch. You know who Dr. Asch  
22 is, right?

23 A. I do.

24 Q. Have you ever read his deposition or any of his prior sworn  
25 testimony?

01:52PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 A. Maybe pieces of it.

2 Q. And you knew Dr. Asch back when he was performing the  
3 retrievability study for the Recovery Filter. Isn't that true?

4 A. Yes. I knew him well.

5 Q. And tell us about your involvement with that pilot study  
6 with Dr. Asch.

01:53PM

7 A. So it's not a pilot study.

8 Q. That's what he calls it.

9 A. It's not true. It's a special access study. And so I was  
10 the person at NMT who liaised with Dr. Asch most of the time.  
11 I have spent a lot of time in Toronto at cases supporting him  
12 however he needed.

01:53PM

13 Q. So you were aware of the fractures and the migrations that  
14 happened in that study?

15 A. I was aware of the one fracture and the one migration that  
16 happened.

01:53PM

17 Q. You weren't aware that there were two fractures in that  
18 study?

19 A. I think they were the same filter is my recollection.

20 Q. Two fractures, though, in the study?

01:53PM

21 A. Okay.

22 Q. For one filter. Do you remember that?

23 A. Yes.

24 Q. And I think you even had meetings with Dr. Asch and Dr.

25 Kaufman about the migration that happened in that study?

01:54PM



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1 A. With others, yes.

2 Q. Now, when you were at NMT --

3 MR. LOPEZ: Can we see trial Exhibit 4554 please?

4 Trial Exhibit 4554?

5 BY MR. LOPEZ:

01:54PM

6 Q. You are familiar with this document?

7 A. I haven't seen it in a long time.

8 Q. It's been about two months.

9 A. I don't recall seeing this, no.

10 Q. Could you go to Page 7 of this document.

01:54PM

11 I'm going to ask you, sir, when NMT was first  
12 designing the Recovery Filter and doing its animal study and  
13 was going to Dr. Asch to do his special access -- is that what  
14 you call it, special access study?

15 A. Yes.

01:55PM

16 Q. It was designed to have -- to look for whether or not the  
17 device could be retrieved safely within 12 weeks. Would you  
18 agree with me?

19 A. The animal study was.

20 Q. And wasn't Dr. Asch's study also designed to determine  
21 whether or not it could be removed within 12 weeks?

01:55PM

22 A. I would have to review the protocol. I don't know for  
23 sure.

24 Q. I believe this one is already in evidence, Your Honor,  
25 4554?

01:55PM

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1 THE COURT: No, it's not.

2 MR. LOPEZ: May I offer it at this time?

3 MR. NORTH: No objection, Your Honor.

4 THE COURT: Admitted.

5 MR. LOPEZ: May I publish it to the jury, Your Honor?

01:55PM

6 THE COURT: Yes.

7 MR. LOPEZ: Can we look at Page 1, Gay, please, so the  
8 jury can get an idea what this is?

9 This is from NMT Medical, Inc., and the date is May  
10 22, 2000.

01:55PM

11 Do you see that, sir?

12 THE WITNESS: Yes, I do.

13 MR. LOPEZ: Can we go to Page 7, please, Gay?

14 And could you make the actual table there larger?

15 BY MR. LOPEZ:

01:56PM

16 Q. And this is about the Recovery Filter. Isn't Dr. Asch's  
17 study already ongoing at this time?

18 A. Yes, I believe so.

19 Q. And this was -- the Recovery Filter was -- the idea was  
20 that it would be a permanent filter that you could remove long  
21 term, meaning 12 weeks. That's how it was defined by NMT when  
22 they did this study, right?

01:56PM

23 A. That was the data we had. This is a presentation to Boston  
24 Scientific back during the time you were talking about when the  
25 litigation was going on.

01:56PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. And the Recovery Filter is the ideal vena cava filter  
2 because it would have the same strengths as permanent filters.  
3 True?

4 A. That's what it says, yes.

5 Q. And it would also involve accurate placement, enhanced  
6 centering, small sheath. Do you see where it says that?

7 A. Yes.

8 Q. And it would be removable at 12 weeks. True?

9 A. Yes.

10 Q. And, in fact, Dr. Asch's study didn't establish safety of  
11 retrievability beyond 12 weeks, did it?

12 A. I think there were many removals far past 12 weeks.

13 Q. There were, but the design, the mean period of time,  
14 meaning the average period of time for retrievability was less  
15 than 12 weeks. True?

16 A. I don't know. I would have to see that.

17 Q. Did it follow patients for more than a year who had the  
18 device in them to see if the devices could be safely removed  
19 after one year?

20 A. Yes. Oh. I think the longest might have been 183 days.

21 Q. That was how many patients?

22 A. That's the longest.

23 Q. One patient?

24 A. That one was, yes.

25 Q. So the best data that Bard had clinically that a Recovery

01:56PM

01:57PM

01:57PM

01:57PM

01:58PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Filter could be safely removed if left in after 12 weeks was  
2 one patient where it was left in for 183 days. True?

3 A. No. I said that was the longest.

4 Q. But did you follow any of these patients after 183 days of  
5 implantation?

01:58PM

6 A. I don't think so, no.

7 Q. So you don't know anything about what happened to those  
8 other patients who did not have their devices removed after 183  
9 days?

10 A. They weren't part of the study, no. I don't know.

01:58PM

11 Q. Well, they weren't part of the study because once the study  
12 was over they were told if they kept it in they were left to  
13 whatever happened to them, right?

14 A. Yes, like all clinical studies.

15 MR. LOPEZ: Can we go to Page 9, please, of this  
16 exhibit. Again, this talks about -- that's Page 9. Let's go  
17 to 21 instead, Gay, please.

01:58PM

18 BY MR. LOPEZ:

19 Q. I think this is the animal study that you mentioned  
20 earlier, I think, that we talked about earlier, isn't this in  
21 the Recovery Filter In Situ six-week residence?

01:59PM

22 A. No.

23 Q. This isn't the animal study? What is this?

24 A. This is a animal study.

25 Q. It's a animal study. Okay. But this is an animal study to

01:59PM

5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct

1 see if it could be removed within six weeks?

2 A. No. This is a study to look at the filter implanted at six  
3 weeks.

4 Q. And then it was removed after six weeks?

5 A. No. They were not all removed.

02:00PM

6 Q. Some of the animals were sacrificed without the device  
7 being removed?

8 A. I don't know in this study. This isn't our study that we  
9 used to support our submission.

10 Q. What does a six-week residence study mean?

02:00PM

11 A. It means the filter was implanted for six weeks.

12 Q. And let's go to the next slide, Page 22. 12 filters  
13 removed from 12 animals. This is a 12-week removal study.  
14 That's what this is talking about, right?

15 A. Yes, it is.

02:00PM

16 Q. And 100 percent of those were successful?

17 A. Yes.

18 Q. And was there ever an animal study done where any of those  
19 devices were left in beyond 12 weeks?

20 A. No.

02:01PM

21 Q. Next slide, please. One more.

22 Now, the human experience would be the Asch study,  
23 correct?

24 A. Yes.

25 Q. Let's look at the presentation here. So this is Dr. Asch.

02:01PM

5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct

1 There had been one removal to date in 10 days. Do you see  
2 that?

3 A. I do.

4 Q. Next slide, please.

5 And then this talks about the plan for there to be a  
6 European -- I'm sorry -- that this would be submitted for a  
7 European -- for a 12-week removal. Do you see that?

02:01PM

8 A. I see it says that. Doesn't say it will be done, was just  
9 a potential.

10 Q. So the regulatory submission in Europe was going to be for  
11 a 12-week removal. That's what it says, correct?

02:02PM

12 A. Potentially.

13 Q. And OUS, what does that mean? Outside the United States?

14 A. It does.

15 Q. That was also going to be a regulatory submission for  
16 12-week removal, correct?

02:02PM

17 A. It says following 12-week removal. I don't know what the  
18 indication was.

19 MR. LOPEZ: Next slide, please. Go back one. 27.  
20 Blow that up, please.

02:02PM

21 BY MR. LOPEZ:

22 Q. This is the U.S. plan for commercialization in 2000. Would  
23 you agree that's what that says?

24 A. This is a potential plan as we are telling a potential  
25 buyer to what could be done with the device.

02:03PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. Right. And in every slide that we have seen thus far, the  
2 plan was for the Recovery Filter to be safe and effective for a  
3 12-week retrievability and thereafter converted to a permanent  
4 device. True?

5 A. No, I don't believe that.

02:03PM

6 Q. You don't believe that's a fair reading of these slides?

7 A. No. The only data we had was a 12-week animal data so  
8 that's what we were representing here.

9 Q. And the human data you had was an average implantation of  
10 53, 54 days.

02:03PM

11 A. No. It was actually only four patients at the time with one  
12 explant of 10 days. So this was very early in the Asch study  
13 as well.

14 Q. I'm talking about later after this, after the animal study.  
15 Dr. Asch just testified here a couple days ago that the mean  
16 retrieval was 53, 54 days. I don't remember exactly. That was  
17 the average period of time that he retrieved devices safely in  
18 his study.

02:03PM

19 A. I'm sorry. Is that a question?

20 Q. Well, do you agree with that?

02:04PM

21 A. I have no idea.

22 Q. Do you disagree?

23 A. I don't know what he said.

24 Q. Sir, you came here today. You knew I was going to ask you  
25 about the Asch study, right? I asked you about it two months

02:04PM

5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct

1 ago.

2 A. You asked me a lot of questions over time.

3 Q. You know how important the Asch study is to this case,  
4 don't you?

5 A. To this case?

02:04PM

6 Q. Yeah.

7 A. No.

8 Q. Well, you have been asked about the Asch study a lot at  
9 depositions and two months ago when you were testifying under  
10 oath?

02:04PM

11 A. That was for a different filter.

12 Q. Okay. But you know how important the Asch study is. Dr.  
13 Asch testifies here you knew he was testifying, right?

14 A. No. I found out he was testifying.

15 Q. And you didn't think it was important for you to come  
16 prepared to discuss the details of the Asch study when I was  
17 asking you questions about that, about important information  
18 that the jury might want to know and maybe should know. True?

02:04PM

19 MR. NORTH: Objection. Argumentative.

20 THE COURT: Sustained.

02:05PM

21 BY MR. LOPEZ:

22 Q. Now, let me ask you some questions about the Patient 9 and  
23 Patient 33 real quickly.

24 There was no root cause analysis ever done on either  
25 one of those two patients. True?

02:05PM



—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 A. No, I don't think that's true.

2 Q. Well, root cause analysis would include what the fix would  
3 be, what the solution would be. Wouldn't it?

4 A. No. Sometimes you can't find a solution.

5 Q. Well, the root cause -- and it's not a root cause analysis 02:05PM  
6 if you don't come up with a solution. That's a definition of a  
7 root cause analysis. True?

8 A. Absolutely not. A root cause analysis is to try and figure  
9 out what happened. It doesn't mean -- excuse me -- it doesn't  
10 mean you will. 02:06PM

11 Q. Why did the Recovery Filter migrate four centimeters after  
12 being challenged by a clot in the Asch study?

13 A. I don't know.

14 Q. Why did it fracture?

15 A. Our hypothesis is that it fractured because of the woman 02:06PM  
16 who the filter was in was pregnant and gave birth to a child.  
17 And we believe that the forces that were put on the filter at  
18 that time probably caused it to fracture.

19 Q. But you didn't do any bench testing or other testing where  
20 you replicated those forces to see if maybe that was the cause 02:06PM  
21 of the fracture?

22 A. I don't remember either way.

23 Q. And once you had a fracture after that Recovery Filter was  
24 on the market, and it was not a pregnant woman, you should have  
25 concluded at that time it wasn't because of a pregnancy. True? 02:06PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 A. If the woman wasn't pregnant we would not conclude that it  
2 was because of a pregnancy. True.

3 Q. And if it happened in a man it certainly wasn't related to  
4 a pregnancy. True?

5 A. Chances are good, yeah.

02:07PM

6 Q. And then after the Recovery was on the market, it started  
7 experiencing similar migrations to the migrations that were  
8 experienced in Dr. Asch's study. True?

9 A. We had migrations.

10 Q. Did you ever figure out why any of those devices were  
11 migrating?

02:07PM

12 A. Yes.

13 Q. And why were they migrating?

14 A. Different ones for different reasons. But normally because  
15 they were overwhelmed by a massive clot.

02:07PM

16 Q. They were relating to the way that the device was designed.  
17 Would you agree with me?

18 A. Yes.

19 Q. And prior to the Recovery Filter being on the market, other  
20 than the Asch study, most of the data that Bard had was done on  
21 what we call bench testing. True?

02:07PM

22 A. We had bench testing. We had animal testing. Then we had  
23 the Asch study. That's the sequence of events.

24 Q. Would you agree that the goal of bench testing is to  
25 replicate a real world. It was what might actually happen in a

02:08PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 real person?

2 A. To the best of your ability for some tests. You can't do  
3 that for everything.

4 Q. But you need to take into consideration foreseeable  
5 circumstances, the environment of use, all of those things.

02:08PM

6 Those should be well studied if you are just going to see  
7 whether or not a device is safe in basically a test tube?

8 A. Yes, to the best of your ability at the time.

9 Q. And Mr. North yet in his opening statement described that  
10 environment, I think, quite accurately and graphically. The  
11 IVC filter is a challenging environment. Would you agree?

02:08PM

12 A. The vena cava is a challenging environment.

13 Q. I'm sorry. The vena cava is a challenging environment.

14 A. We've come to learn that, yes.

15 Q. And he also said that it's a harsh and dynamic environment.

02:09PM

16 Do you agree with that?

17 A. Yes.

18 Q. This is not a stationary tree trunk. Do you agree with  
19 that?

20 A. Sure.

02:09PM

21 Q. All sorts of stresses happen in the vena cava when you are  
22 trying to design one of these filters. Do you agree with that?

23 A. Yes.

24 Q. You have flattening?

25 A. You can.

02:09PM

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1 Q. You have cross-sectional expansion?

2 A. Yes, you can.

3 Q. And you have longitudinal stress. True?

4 A. Yes.

5 Q. And those are things that were well known about the vena  
6 cava filter 15, 16 years ago. True?

02:09PM

7 A. Absolutely not.

8 Q. When you say "absolutely not" you mean there was no  
9 textbook, there was no doctor, there was nothing that you could  
10 reference that would show how the vena cava acts in a human  
11 body?

02:10PM

12 A. Not to my knowledge, no.

13 Q. Did you do any research yourself?

14 A. We did plenty of research altogether.

15 Q. And you learned later -- so you learned after you tested  
16 and put the device on the market about this dynamic and  
17 challenging and harsh environment in which a vena cava was  
18 being implanted?

02:10PM

19 A. We learned new things for sure, and we always do based on  
20 new imaging, based on experience.

02:10PM

21 Q. And would you also agree that a PVC pipe with sausage  
22 casing as the test environment for an IVC filter is not the  
23 type of environment that Mr. North described in his opening  
24 statement?

25 A. I don't understand. Sorry.

02:10PM

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1 Q. Well, in other words, a rigid PVC pipe with a sausage  
2 casing is not a challenging, harsh, environment, dynamic  
3 environment like Mr. North described in his opening statement.  
4 True?

5 A. If you are speaking of the migration study, it's not a 02:11PM  
6 rigid PVC tube. It does have sausage casing in it which does,  
7 in fact, mimic the vena cava as best we can. And it is a  
8 pretty harsh environment, because you are trying to make the  
9 device move.

10 Q. And that's how it should be tested in its Environment of 02:11PM  
11 Use?

12 A. That's how it is tested for the last 20 years.

13 Q. No, I mean it should be tested -- well, that's not how it  
14 was tested after it was put on the market and put in a real  
15 human being. You didn't test it in a test tube in a sausage 02:11PM  
16 casing that mimicked the human condition, did you?

17 A. We tested exactly what I just described long before the  
18 filter was ever on the market, yes.

19 Q. And it's your testimony that PVC pipe and sausage casing is  
20 mimicking the real condition of a human being's vena cava? 02:12PM

21 A. No, I'm not saying that because it didn't use PVC pipe,  
22 first of all.

23 Q. What kind of pipe was it?

24 A. It's a silicone tube with sausage casing put in, and yes,  
25 the sausage casing does mimic the vena cava because it gives 02:12PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 the hooks of the filter a place to engage that is a natural  
2 material. It's not a vena cava filter. But it is the best we  
3 can do to make a test that you can do time and time again to  
4 compare to.

5 Q. Okay. Now, when you ran those tests with the Recovery  
6 Filter, the bench test you just described, there was no --  
7 there didn't seem you had any issues with migration when  
8 challenged by a clot. True?

02:12PM

9 A. I don't know what you mean by "issues."

10 Q. You didn't have the test, run the test, and after you ran  
11 the test you say, well, the way this is designed when it gets  
12 challenged by a clot it's going to push the filter off its  
13 current location?

02:12PM

14 A. Of course we did. That's the goal of the test.

15 Q. So you thought you had migration issues with the Recovery  
16 Filter when you were testing it on the bench?

02:13PM

17 A. No. The goal of the test is to determine the force or  
18 pressure at which every filter migrates. We want it to migrate  
19 in that test.

20 Q. Okay. I understand. But after running those tests, you  
21 determined that from a migration resistance standpoint the  
22 Recovery Filter was safe to implant in a human being?

02:13PM

23 A. Yes.

24 Q. Yes or no?

25 A. Because they met the internal acceptance criteria.

02:13PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. So you determined after running the test that based on the  
2 results of that test, we can implant these in human beings.  
3 True?

4 A. No. We did a lot of other tests first.

5 Q. Then once you -- but all those other tests that you did  
6 resulted in you determining that this device can at least be  
7 implanted in patients in Dr. Asch's study. True?

02:13PM

8 A. After all of the testing we did on the bench and in the  
9 animals, yes.

10 Q. Okay.

02:14PM

11 A. We applied for a special access study and were granted  
12 that.

13 Q. All right. Now, the first time that the device gets  
14 challenged by a clot in Dr. Asch's study, it starts to migrate  
15 towards the heart. You are aware of that happening, right?

02:14PM

16 A. It did migrate, yes.

17 Q. In fact, I think you agreed when we asked you this question  
18 that if this patient wasn't in a clinical study and being  
19 closely monitored there was some concern that that clot could  
20 have continued up and went into the patient's heart?

02:14PM

21 A. The concern was if we didn't know what could happen to the  
22 filter.

23 Q. Right. And it was a good thing that he was being closely  
24 monitored in a clinical trial. Right?

25 A. Yes. That's how we observed it.

02:14PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. Now, sir, this simple question, didn't that human  
2 experience give you folks at Bard evidence that however you  
3 were testing it in a laboratory was not giving you the kind of  
4 results that would happen in a real human being?

5 A. No.

02:15PM

6 Q. Okay. So you were anticipating this migration that  
7 happened in Patient Number 9, the first and only patient that  
8 was challenged by a clot in the Asch study? Yes or no, sir.  
9 Would you anticipating that happening?

10 A. I can't answer that question yes or no.

02:15PM

11 Q. And Mr. North said in his opening statement that Bard's  
12 process is to learn from their clinical experience. We  
13 assessed our experience with Recovery and created the G2.

14 That experience, that clinical experience with the  
15 Recovery happened after it was launched on to the open American  
16 marketplace. True?

02:16PM

17 A. Partially.

18 Q. When you say "partially," I don't understand what you mean.  
19 Was there another clinical trial going on that we don't know  
20 about after it was launched?

02:16PM

21 A. No. We had the Asch study that we talked about and we had  
22 the commercial experience.

23 Q. I'm talking about after it was launched, the only clinical  
24 experience that Bard was using to assess the performance of the  
25 Recovery Filter was what was happening in the open marketplace.

02:16PM



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1 True?

2 A. Yes.

3 Q. And doctors weren't being told to follow these patients so  
4 that they could report back to Bard how they were performing.

5 It would be up to a doctor to voluntarily report those events  
6 if he or she decided it was something they should report.

02:16PM

7 True?

8 A. Which is true for everything.

9 Q. Well, sir, is that true or not, that Bard was not following  
10 these patients. They were relying on doctors, other doctors to  
11 follow the patients and maybe report those back to Bard. True?

02:17PM

12 A. Yes. That's true. Doctors monitor their patients, we  
13 don't. And if they choose to report to us, they will.

14 Q. Right. But Bard didn't put out, when they put the Recovery  
15 Filter out in the market, tell doctors I want you to monitor  
16 these patients and let me know if you see a fracture like we  
17 saw in the Asch study. Let me see if you see a perforation or  
18 a tilt like we saw in the Asch study, or let me know if you see  
19 fractures like we saw in the Asch study. Bard never gave those  
20 instructions or that information or advice to doctors. True,  
21 sir? Yes or no? Can you answer that yes or no?

02:17PM

02:17PM

22 A. No, I can't.

23 Q. Before Bard launched the G2, did it have -- did it do any  
24 clinical study at all on the G2?

25 A. Not before we launched as a permanent, no.

02:18PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. So before it went into the open marketplace, you didn't  
2 even do an access, special access study like what you did with  
3 the Recovery Filter. Right?

4 A. No, we did not.

5 Q. You did some bench testing. You made some design changes  
6 to it. You changed the name from the Recovery to the G2, and  
7 you launched it?

02:18PM

8 A. No. That's not what we did.

9 Q. You didn't do any clinical trial work, did you?

10 A. No, we did not.

02:18PM

11 Q. You had no idea how it was going to react and respond in  
12 patients before it was launched. True?

13 A. No.

14 Q. That's not true?

15 A. Correct.

02:19PM

16 Q. You actually had -- you actually knew how it was going to  
17 react and respond in patients before it was launched?

18 A. We had testing that showed it was significantly better than  
19 its predicate device.

20 Q. You had bench testing.

02:19PM

21 A. And we had animal testing.

22 Q. You had animal testing. What kind of animal testing?

23 A. The exact same tests we did in Recovery.

24 Q. Which was?

25 A. 12-week implant and removal for safety. The idea of the --

02:19PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. I'm sorry. I just want to make sure we're on the right  
2 page. Before the permanent device was launched?

3 A. Yes. We did animal work to show that when you remove the  
4 device that it doesn't significantly damage or in any way harm  
5 the vena cava. That's the risk of removal.

02:19PM

6 Q. Okay. My question was that's to determine whether it's  
7 retrievable. Was there any clinical, human clinical data on  
8 its safety and effectiveness as a permanent device?

9 A. No.

10 Q. Before it was launched?

02:20PM

11 Okay. So it was launched without any clinical data  
12 about long term safety and effectiveness as a permanent device.  
13 True?

14 A. Yes, but it relies on its predicate also.

15 Q. And then without having any clinical data on the G2 Filter  
16 before it was launched, did you advise physicians who might be  
17 prescribing the G2 Filter that they ought to monitor those  
18 patients closely since -- and see whether or not the G2 is  
19 actually going to perform safer than our Recovery Filter? Did  
20 you give that advice to doctors? Yes or no?

02:20PM

02:20PM

21 A. No.

22 Q. Before -- by the way, we talked a little bit about the  
23 sales force and the marketing department. And Mr. O'Connor  
24 talked to Mr. Modra about it a little bit today. The face of  
25 the company, the people that interact most with doctors and

02:21PM

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1 hospitals are the sales force, right?

2 A. Sure.

3 Q. They are in doctor's offices every day?

4 A. Hopefully.

5 Q. And their purpose is to sell Bard products, including IVC  
6 filters. Right?

02:21PM

7 A. The ones who sell filters, yes.

8 Q. And if doctors have questions -- by the way, do you know  
9 what fair balance means when it comes to marketing and selling  
10 medical devices?

02:21PM

11 A. Yes.

12 Q. What does that mean? Explain that to the jury please.

13 A. That your promotional equipment or your promotional  
14 documents are fair and balanced to competition.

15 Q. And they must be fair and balanced, meaning you can't just  
16 tell them how wonderful the device is. If you have information  
17 about risks that doctors don't know about, you have to tell  
18 them about those risks so that they can do a risk benefit  
19 analysis themselves. True?

02:22PM

20 A. Not in a marketing brochure, no, I don't think so.

02:22PM

21 Q. No, but I thought when you are marketing, when your  
22 salespeople are having conversations with doctors?

23 A. Those are in the IFU.

24 Q. When they are having conversations with doctors,  
25 salespeople should be armed with data about Bard filters in

02:22PM

5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct

1 case the subject comes up about the safety and effectiveness of  
2 Bard filters. True?

3 A. Generally, yes.

4 Q. And if there is information that might influence a doctor  
5 to not use a Bard filter over safety concerns, and only Bard  
6 has that information, Bard ought to arm their salespeople with  
7 that information to share with doctors. Yes or no?

02:22PM

8 A. Can't answer that yes or no. It's a hypothetical question.

9 Q. Mr. North's comments about clinical experience, how the  
10 company learns how a product's performing because they are  
11 getting information about their clinical experience as it's  
12 being sold, that clinical experience that Bard's learning about  
13 is probably clinical experience that doctors ought to know  
14 about, too. Don't you agree?

02:23PM

15 A. In general.

02:23PM

16 Q. And you have information. We went over some complaint  
17 files earlier today. Bard doesn't only get reported, we had a  
18 fracture, they are supposed to investigate fractures. They are  
19 supposed to contact the health care provider and learn as much  
20 as they can about these complications. True?

02:24PM

21 A. About every complaint, not just fracture.

22 Q. Right. And the reason they do that is because they might  
23 learn something about their performance of their device that  
24 may cause them to maybe reconsider the design of the product.

25 True?

02:24PM

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1 A. Of course. We use that data all the time to improve  
2 devices constantly, no matter what the device is. That is the  
3 primary form of feedback when the device is commercial.

4 Q. And, sir, wouldn't you agree that if it was important  
5 information for Bard to learn about for purposes of whether or  
6 not they might want to redesign their product for a safety  
7 reason that that same information would be important to pass on  
8 to doctors and patients. Yes or no?

9 A. If it were for safety, yes. But we're not talking about  
10 safety for every complaint.

11 Q. But certainly if it dealt with a safety concern, an injury  
12 that doctors may not appreciate about your device, that's  
13 certainly something that you ought to pass on to doctors so  
14 that they know about it. Right?

15 A. No. I don't agree with that in general.

16 Q. Well, sir, aren't you -- you know that doctors sometimes  
17 will have a bad experience with a device, and if they share  
18 that experience with one of their colleagues they may cause  
19 both of those doctors to not use that device again. You are  
20 aware of that, right?

21 A. Yes.

22 Q. As a matter of fact, you were aware of that in 2005 when  
23 you and Janet Hudnall decided it would be a good idea for her  
24 to go out and interview some of Bard's most significant  
25 customers, physicians who were having issues with the Recovery

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1 Filter. True?

2 A. No. It wasn't me and Janet Hudnall.

3 Q. Let's look at Trial Exhibit 0753. While she's calling that  
4 up, Mr. Carr, I apologize. I know it's on the screen, but let  
5 me ask you a question.

02:26PM

6 You said not every report, but certainly, if there  
7 were reports or a trending of reports that involved tilt,  
8 migration, perforation, fractures, embolization of pieces of  
9 the device to the heart or lung, that would be the kind of  
10 information that would be relevant information for other  
11 doctors to know about. True?

02:26PM

12 A. Only if it reached a certain level, if there was a safety  
13 risk.

14 Q. I'm talking about information that might influence a doctor  
15 to not use your device because of an experience of another  
16 doctor. You are familiar with that concept, aren't you, as a  
17 former marketer?

02:27PM

18 A. I have never been a marketer.

19 Q. You are familiar with that concept?

20 A. That if somebody talks to somebody also and they choose not  
21 to use it? Yes.

02:27PM

22 Q. Right. And if you look at Trial Exhibit 753, and I can  
23 show you the deposition. But you were the 30(b)(6) witness for  
24 this particular event?

25 A. I don't have that exhibit.

02:27PM

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1 MR. LOPEZ: Will you stipulate to that, counsel?

2 THE COURT: Mr. Lopez, let's ask questions of the  
3 witness not of counsel.

4 MR. LOPEZ: I'm going to have to look at the  
5 deposition then, Your Honor. This is the October 29, 2014  
6 deposition, Trial Exhibit 753. Actually, let's not do that.  
7 Let's just look at the document. I think I can lay a  
8 foundation with this witness.

02:27PM

9 Gay, I'm sorry, could you put back up Trial Exhibit  
10 753? Oh. 755. Apologize.

02:28PM

11 BY MR. LOPEZ:

12 Q. Do you have 755 in front of you?

13 A. Yes.

14 Q. You are familiar with this e-mail and these events?

15 A. Yes.

02:28PM

16 Q. ?

17 A. I don't know if I have seen this e-mail. I guess I have in  
18 a previous deposition.

19 Q. We can go to the next page. Might help you.

20 A. Yes.

02:29PM

21 Q. Okay. And did you have a meeting with Janet Hudnall about  
22 the events that are described in this e-mail?

23 A. I don't recall one. I'm not on this e-mail anywhere.

24 THE COURT: We're going to break at this point, Mr.  
25 Lopez.

02:29PM



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1 Ladies and Gentlemen, we will resume at 2:45. I will  
2 excuse you.

3 (Recess from 2:29 p.m. until 2:47 p.m.)

4 You may continue, Mr. Lopez.

5 BY MR. LOPEZ:

02:47PM

6 Q. We were talking about Exhibit 755, Mr. Carr. I think it  
7 should be still on your screen. Anyway, you are familiar with  
8 this event that's described in this document, this road show,  
9 the G2 road show, correct?

10 A. I'm familiar with the document, yes.

02:47PM

11 MR. LOPEZ: Go to, Gay, Number 3 of the document  
12 755-03.

13 Your Honor, may I offer this into evidence at this  
14 time and ask that it be published to the jury?

15 MR. NORTH: No objection, Your Honor.

02:48PM

16 THE COURT: Admitted, and you may publish.

17 MR. LOPEZ: Thank you.

18 And Gay, would you please enlarge the first full  
19 paragraph of Page 3 of this exhibit.

20 BY MR. LOPEZ:

02:48PM

21 Q. And this is from -- you can see this is from Janet Hudnall.  
22 Do you see that?

23 A. Yes.

24 Q. And Janet writes -- and just to give the jury the proper  
25 perspective and date, this is in July of 2005. Can you confirm

02:48PM

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1 that, sir, from the e-mail?

2 A. No, I can't.

3 MR. LOPEZ: Go back to Page 1, Gay, please. March of  
4 '05. Go to Page 2.

5 BY MR. LOPEZ:

02:49PM

6 Q. Okay. This is in March of 2005. Do you see that?

7 A. Yes.

8 Q. And that's about the time when Bard was already redesigning  
9 the Recovery to become the G2, to replace the G2 on the  
10 marketplace because of some safety issues regarding the  
11 Recovery Filter. True?

02:49PM

12 A. I think it's just before the release of it.

13 Q. And actually, the intent was to release it then but it  
14 didn't release until a few months later. Right?

15 A. I don't know for sure.

02:49PM

16 Q. And Janet writes: As we gear up for the release of the  
17 modified Recovery. So the jury understands what that means,  
18 modified Recovery is the G2, correct?

19 A. Yes, it is.

20 Q. One of the things I'm going to do is personally visit those  
21 accounts that need a little extra attention and formally  
22 introduce the modifications.

02:49PM

23 Do you see that?

24 A. Yes.

25 Q. And what she means by that, these are people who have been

02:50PM

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1 using or known to have been customers of Bard who were using  
2 the Recovery device?

3 A. I assume so.

4 Q. And these could be accounts that have been skeptical but  
5 have large potential upside or high profile accounts that could  
6 affect other accounts in the area.

02:50PM

7 Do you see that?

8 A. Yes.

9 Q. In other words, there was a concern that some of the  
10 doctors who may have been having some bad experiences with the  
11 Recovery Filters might share with their experience with other  
12 doctors that could affect other doctors using the Recovery  
13 Filter. Do you agree with that?

02:50PM

14 A. I agree that could be a concern. I also think that she's  
15 being proactive and introducing the new device to potential  
16 clients.

02:50PM

17 Q. Okay. We'll see.

18 MR. LOPEZ: Let's go to the next page, Gay, please.

19 BY MR. LOPEZ:

20 Q. Okay. So now, this is September of 2005. And if you look  
21 at the first full paragraph, this is still talking about the G2  
22 Filter road show. Do you know why it was called a road show?

02:51PM

23 A. She was going different places on the road. I don't know.

24 Q. And she was getting a list of the accounts from her various  
25 district managers as to whom they believed should be the

02:51PM

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1 customers for her to go visit. Correct?

2 A. It says a list of road show accounts, yes.

3 Q. And let's go to the next page, please. Keep going.

4 And is this a list of the various accounts and  
5 hospitals that Janet was asking for to have -- to be able to  
6 determine who to go visit about the Recovery and G2 Filter?

02:52PM

7 A. I don't know. I assume so.

8 THE COURT: Folks, somebody has their phone on. If  
9 you could all please turn your phone off, not just on mute.  
10 That buzzing we're hearing is a phone interfering with the  
11 system.

02:52PM

12 MR. LOPEZ: Excuse me one second. Let's try Trial  
13 Exhibit -- is this part of 755 now? Okay.

14 I apologize, Your Honor.

15 BY MR. LOPEZ:

02:54PM

16 Q. Exhibit 755, Page 14, do you recognize this document, sir?

17 A. I have been shown it before, yes.

18 Q. And this is the priority accounts that were discussed in  
19 the earlier e-mails. True?

20 A. Probably. I'd have to check.

02:55PM

21 Q. Okay. And these -- this is the information that Janet  
22 Hudnall was gathering as she was doing her G2 road show?

23 A. I assume so.

24 Q. And these are -- when western region G1A Recovery, that's  
25 referring to the G2. In other words, if you see G1A in some of

02:55PM

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1 these documents, it actually refers to the G2?

2 A. Yes.

3 Q. And these are priority. Priority accounts would be what?

4 A. You would have to ask her.

5 Q. And these are like say, for example, this first doctor,  
6 he's from Austin, Texas. And the annual value, I mean, the  
7 annual volume is listed so before she went out she knew how  
8 much value that these particular doctors had to Bard, correct?

02:55PM

9 A. Of course. We know all of our data.

10 Q. And this doctor just heard of a migration, just heard about  
11 it, and that was enough for him to not use the Recovery Filter?

02:56PM

12 MR. NORTH: Objection, Your Honor. 602.

13 THE COURT: Overruled. The witness can answer if he  
14 knows.

15 THE WITNESS: I have no idea.

02:56PM

16 BY MR. LOPEZ:

17 Q. Isn't that how you would interpret that under comments,  
18 that Dr. Reifsnyder heard of migration and won't use?

19 A. That's what the document says.

20 Q. And another doctor from DeMoines, Iowa, he got a letter and  
21 just from getting a letter he had a fear about the migration  
22 problems with the Recovery Filter. See that?

02:56PM

23 A. I do.

24 Q. And then there's a doctor who is from California whose name  
25 is redacted, and he stopped using it due to several reported

02:56PM

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1 complications, just reported complications. And that doctor  
2 stopped using it, right?

3 A. I don't know if he stopped. That's what it says.

4 Q. This document, the purpose of this document, the reason I'm  
5 using it, this gives Bard insight and puts Bard into the minds  
6 of what's important to doctors about their devices and what  
7 information they need about their devices to know whether or  
8 not they want to continue to use the device. Whether or not  
9 it's the right judgment by the doctor or not, this is the  
10 information that doctors want. True?

02:57PM

02:57PM

11 A. No.

12 Q. Let's go to the next page, please. Here's a doctor from  
13 Missouri, an \$80,000 account. He stopped using it because of a  
14 migration, correct?

15 A. I don't know. That's what the document says.

02:57PM

16 Q. And another doctor from, also from Springfield, well from  
17 Missouri, \$156,000 account, stopped using. He was just  
18 concerned about reported incidents. Do you see that?

19 A. I do.

20 Q. And next one, San Diego, California, 100,000, standard of  
21 care no longer Recovery concerned about patient safety.

02:58PM

22 Did I read that correctly?

23 A. You did.

24 Q. Let's go to the next page. Here's a doctor in Tennessee,  
25 \$200,000 account, had filter fracture and seen several arms

02:58PM

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1 outside the caval wall. Do you see that?

2 A. Yes.

3 Q. All right. And then there's a doctor from Tennessee, heard  
4 of a migration as leery, meaning he's concerned about whether  
5 or not he's going to use the device. Is that how you interpret  
6 that?

02:58PM

7 A. Yes, concerned. However you want to put it.

8 Q. If we go through this document --

9 MR. LOPEZ: Let's go to Page 6 of 10 of the chart,  
10 Gay, please. One more.

02:59PM

11 BY MR. LOPEZ:

12 Q. And if you look at -- let's go down near the bottom. There  
13 are doctors now in Tampa, Florida, who had fracture concerns  
14 about the Recovery Filter. Do you see that, sir?

15 A. I do.

02:59PM

16 Q. And then there's a doctor who stopped using migration from  
17 Missouri. Let's go one more page.

18 Anyway, this is -- you can glean from looking at this  
19 that doctors aren't waiting for certain levels of percentages  
20 or statistics, or whether or not it's consistent with an old  
21 device where something was reported in the medical literature.  
22 They are interested in what's going on with a device currently.  
23 And every doctor, for different purposes and different reasons,  
24 could choose to stop using, particularly a new medical device,  
25 just based on information he's hearing from other doctors.

03:00PM

03:00PM

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1     Wouldn't you agree with that?

2     A.   Of course.   Anybody can do anything.

3     Q.   But one of the advantages Bard has over doctors that are  
4     just in an office in Missouri or in Tennessee, those doctors  
5     only have access to their own local experiences.   Bard's  
6     getting information about the experience of doctors literally  
7     from all over the world.   Isn't that true?

03:01PM

8     A.   Yes.

9     Q.   I mean, so a doctor -- the doctor in Tennessee who heard  
10    about one migration and doesn't want to use it in anymore, he  
11    has no idea that there may have been 10 other doctors in other  
12    parts of the country who, before he had that one migration,  
13    each had a migration because they only reported it to Bard and  
14    Bard never reported that to that doctor.   True?

03:01PM

15    A.   No.

03:01PM

16    Q.   So Bard does report the experiences of other doctors as it  
17    accumulates all of this complaint data?

18    A.   No, we don't.   We would only act if it became unexpected.

19    Q.   Well, sir, I understand what your protocol is.   But for  
20    patient safety purposes, what's important is what is the  
21    protocol of physicians and doctors?   What do they think is  
22    important?   What's relevant to them?   What risk are they  
23    willing to accept?   Wouldn't you agree with me, sir?

03:02PM

24    A.   That's not a question.   I'm sorry.

25    Q.   Would you agree with me that that's what's important?

03:02PM



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1 A. No. You would have to ask the physicians.

2 Q. Well, you have got a number of physicians, at least you see  
3 from this road show that are telling Bard that just because  
4 they heard about a migration or they have had one migration and  
5 they are not using the device anymore, you know that there are  
6 doctors like that around the country. Right?

03:02PM

7 A. Yeah. They are listed here.

8 Q. But again, Bard has the advantage of having gathered the  
9 information from every doctor or hospital that's reported these  
10 adverse events to Bard. You have it all, right?

03:03PM

11 A. We have what we were given, yes.

12 Q. And it's not Bard's policy to share that data with other  
13 physicians to whom they are selling their medical devices,  
14 right, including an IVC filter?

15 A. We don't share each and every report, no.

03:03PM

16 Q. In fact, you don't share any of your test results with any  
17 customer that might support your claims. Right?

18 A. We supply our adjudicated clinical trial data.

19 Q. So if a doctor, we talked about this before, in the G2  
20 brochure when you make claims about your device being -- taking  
21 strength and stability to a new level, where it says data on  
22 file, if a doctor calls up and asks for that data Bard doesn't  
23 give that to the doctor?

03:03PM

24 A. Correct, because that data is kind of the secret sauce to  
25 the device, those specifications, those dimensions, those

03:04PM

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1 performance criteria are what makes our device our device. And  
2 it is a highly patented area, and there is stiff competition.  
3 So no we would not provide that generally to a physician.

4 Q. How about when you have focus groups with some of your  
5 consultants and they give you advice about what they think the  
6 fracture rate and the migration rate and the death rate should  
7 be about filters. Do you share that information with doctors  
8 to whom you are selling sometimes \$200,000 worth of IVC  
9 filters?

03:04PM

10 A. I don't know what Janet shared with them.

03:04PM

11 Q. You have had focus group with doctors before in the middle  
12 of the G2 being on the market and having issues with the G2  
13 migrating and fracturing, right?

14 A. So we didn't have issues with the G2 migrating and  
15 fracturing, but yes, we did convene two separate panels to  
16 investigate bariatric patients, which are people who have  
17 gastric bypass surgery, and then also to discuss caudal  
18 migration.

03:05PM

19 MR. LOPEZ: Could we see Exhibit 1452 and 1033 at the  
20 same time. For some reason they are two separate exhibit  
21 numbers but they are actually the same document. One is Page 1  
22 and one is Page 2.

03:05PM

23 BY MR. LOPEZ:

24 Q. Sir, we talked about this document, 1452, two months ago.  
25 Do you recall that?

03:05PM

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1 A. We talked about a different version of this document.

2 Q. Okay. It was a version -- you said that was -- what do you  
3 mean a different version of this document? I'm confused.

4 A. The document you showed me last time had notes all over it.

5 Q. This is the same exhibit.

03:05PM

6 A. I don't believe that's correct.

7 Q. Let's look at 1033. Maybe I'm confused. Are you saying  
8 this isn't the document you saw two months ago?

9 A. Yes. I am saying that.

10 Q. How about the document that's in front of you now?

03:06PM

11 A. I don't remember you showing me this page.

12 Q. Do you recall this document refreshing your recollection  
13 that one of your consultants thought that the Recovery --

14 MR. NORTH: Objection. He's reading from the content  
15 of the document. It's not admitted.

03:06PM

16 THE COURT: You can't read from a document that's not  
17 in evidence.

18 MR. LOPEZ: I'm not. I'm reading from my notes.

19 THE COURT: Looked like you were reading from the  
20 document.

03:06PM

21 BY MR. LOPEZ:

22 Q. Did any of your key opinion leaders ever refer to a  
23 Recovery Filter as a wimpy filter?

24 A. Yes.

25 Q. Was that Dr. Venbrux?

03:07PM

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1 A. I don't know. The statements on the first page, I believe  
2 it was Dr. Kaufman.

3 Q. Okay. And this was an expert panel that you had put  
4 together to talk about issues that you were having with the  
5 Recovery Filter at that time, right?

03:07PM

6 A. I have no idea where this document came from.

7 Q. You testified about this document in March of 2018. That  
8 was two months ago. You didn't remember doing that two months  
9 ago?

10 A. Yes. And I told you then I don't know where the document  
11 came from.

03:07PM

12 MR. LOPEZ: Could we look at the Kevin Phillips, Page  
13 187. Show it to Mr. Carr, please.

14 How do I switch this, Traci?

15 BY MR. LOPEZ:

03:08PM

16 Q. Sir, this is the testimony you gave in February of 2015.  
17 It was about the meeting that's represented on Trial Exhibits  
18 1452 and 1033.

19 MR. NORTH: Your Honor, I'm going to object to  
20 counsel's statement. There's been no testimony linking that  
21 document to any meeting, and it's not admitted.

03:09PM

22 THE COURT: Mr. Lopez, your response.

23 MR. LOPEZ: I will have to give him another -- hold on  
24 a second.

25 BY MR. LOPEZ:

03:09PM

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1 Q. Let me ask you, we're not showing this to the jury. Does  
2 this refresh your recollection that you acknowledge this  
3 document and acknowledge being at this meeting?

4 THE COURT: You have to have an exhibit number for  
5 whatever you are showing. 03:09PM

6 MR. LOPEZ: I can only refer to it as Phillips. Is  
7 there an exhibit number?

8 MS. SMITH: It's a trial transcript.

9 THE COURT: You have to give it an exhibit number if  
10 it's going to be referred to in this trial. 03:09PM

11 MR. LOPEZ: Could we give this an exhibit number?

12 THE COURT: What is it you are asking to have  
13 admitted?

14 MR. LOPEZ: Transcript.

15 THE COURT: One Page? 10 pages? 100 pages? 03:10PM

16 MR. LOPEZ: Three pages.

17 THE COURT: What's the date of the transcript?

18 MR. LOPEZ: Let me get a cover page. February 4 and  
19 5, 2015.

20 THE COURT: All right. Do you want to bring that to  
21 Traci and she can mark it as an exhibit? 03:10PM

22 MR. LOPEZ: Your Honor, just in the interest of time,  
23 I'm going to pass on this. We'll do this at some other time.  
24 We don't need to do this right now.

25 THE COURT: That's fine. 03:10PM

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1 BY MR. LOPEZ:

2 Q. Let's move on. In any event, you don't remember being at a  
3 meeting with Dr. Venbrux, Dr. Kaufman, and others about the  
4 Recovery Filter?

5 A. I have had many meetings with Dr. Kaufman and Dr. Venbrux.  
6 I don't remember that meeting, no. 03:11PM

7 Q. Now, when Janet Hudnall went out in 2005 right before the  
8 Recovery Filter, Bard was going to stop marketing the Recovery  
9 Filter and start marketing the G2 Filter. When she called on  
10 these doctors the Asch study had already been done, right? 03:11PM

11 A. Yes.

12 Q. You had already had three or four health hazard evaluations  
13 regarding some problems with migration and fractures of the  
14 Recovery Filter. True?

15 A. I don't know. 03:11PM

16 Q. You don't remember that?

17 A. I don't know how many, no.

18 Q. But you had some health hazard evaluations that related to  
19 fractures and migrations of the Recovery Filter?

20 A. We have over time. I don't know those dates. 03:11PM

21 Q. Why don't I show you one. Can I have the June 2004 HHE,  
22 please, 1219. Trial Exhibit 1219.

23 While we're doing this, Mr. Carr, what's a health  
24 hazard evaluation? And why does a company have to do one of  
25 those? 03:12PM

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1 A. I don't know the definition of it. It is a the health  
2 hazard evaluation so when there's something that wants to be  
3 evaluated from a health and safety point of view, they put  
4 together these documents.

5 Q. And you have seen health hazard evaluations as they relate  
6 to the Recovery Filter?

03:13PM

7 A. I have seen some.

8 Q. And you have seen the one that's on the screen?

9 A. I don't know.

10 Q. But a health hazard evaluation is a report of a document  
11 that's kept in the ordinary course of business at Bard and  
12 distributed among other members of Bard as they are evaluating  
13 the risk and hazards of one of their IVC filters. True?

03:13PM

14 A. It is not widely distributed, no.

15 Q. Meaning it goes to people who should know about these  
16 events in the event that they are in a position to maybe do  
17 something to improve the product, or to potentially save  
18 people's lives. Right?

03:13PM

19 A. No. It does not go to everyone, no.

20 Q. I didn't say everyone. It goes to important people who are  
21 decision makers at Bard?

03:14PM

22 A. No. For example, I didn't see a lot of them.

23 Q. But does it go to other people other than you maybe who  
24 would be important people who would be making important patient  
25 safety decisions about their products?

03:14PM

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1 A. It goes to a very small group of people.

2 Q. David Ciavarella is the medical director, right?

3 A. I don't know if he was at that time.

4 Q. And who is Doug Uelmen?

5 A. He was the vice president, I believe, of quality affairs.

03:14PM

6 Q. And who is John Lehmann?

7 A. He was a consultant.

8 Q. And again, what is the purpose of a health hazard

9 evaluation? I'm not sure you told us that. What is the

10 purpose of it?

03:14PM

11 A. I did tell you. It is to an assess when there is an

12 occurrence that people want to do a deeper dive or assess from

13 a health hazard point of view.

14 Q. There's concerns about the safety and the performance of

15 the device, right?

03:15PM

16 A. They want to investigate what happened.

17 MR. LOPEZ: Your Honor, I'd like to offer Exhibit 1219

18 at this time. There's some redactions that have to be made but

19 I'm not going to deal with that right now. I won't show that

20 part of it that I know have to be redacted.

03:15PM

21 MR. NORTH: No objection to the admission subject to

22 the redactions.

23 THE COURT: All right. 1219 is admitted.

24 MR. LOPEZ: Your Honor, just to be safe I'm going to

25 ask Gay to just blow up the description of the problem which I

03:15PM



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1 think is safe from the issue that we're talking about.

2 And Gay can you also just show the top part of that?

3 Hold on one second. Yeah. You can do that. Just so the jury  
4 can see what date this is and what it is.

5 BY MR. LOPEZ:

03:16PM

6 Q. And this is an updated health hazard evaluation?

7 THE COURT: Do you want this displayed?

8 MR. LOPEZ: Yes, Your Honor. Publish to the jury,  
9 please.

10 THE COURT: All right.

03:16PM

11 BY MR. LOPEZ:

12 Q. So this would indicate that is an update to two prior  
13 health hazard evaluations performed for the same hazards by Dr.  
14 John Lehmann. They call this a hazard, right? Those are  
15 Bard's words?

03:16PM

16 A. Yes.

17 Q. And these HHEs were submitted as part of a remedial action  
18 plan on March 10 and April 27, 2004?

19 A. That's what it says.

20 Q. And the update includes information from all reported cases  
21 of migration of the Recovery Filter through June 29, 2004.

03:16PM

22 Correct?

23 A. Yes.

24 Q. Now, I know that the Recovery Filter was on the market for  
25 about a year, virtually the entire year 2003. But the real

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1 launch where Bard went out and they organized and they had what  
2 they called their full market launch happen in January of 2004.  
3 Isn't that true?

4 A. No.

5 Q. If there's a document that says that -- if we have two  
6 documents that say that are the documents wrong?

03:17PM

7 A. I don't know what documents you are speaking of. But there  
8 was no full market release of the Recovery Filter.

9 Q. There's never been a full market release of the Recovery  
10 Filter?

03:17PM

11 A. That's my understanding.

12 Q. Let's go to the section that I have highlighted or the  
13 description of the problem. Okay. Now, again, this is -- Dr.  
14 Ciavarella is the only doctor in Bard that is working on this  
15 health hazard. True?

03:18PM

16 A. I believe Dr. Lehmann did the health hazard.

17 Q. Dr. Ciavarella, I think, did this one if you look at the  
18 first part.

19 A. No, I don't agree.

20 Q. So it says from Dr. Ciavarella, but it's really not from  
21 Dr. Ciavarella?

03:18PM

22 A. The note is from Dr. Ciavarella. I think the evaluation  
23 clearly stated it's by Dr. John Lehmann.

24 Q. Okay. Well, that's really not that important.

25 The first sentence says: This HHE is an update to two

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1 prior HHEs performed for the same hazard by Dr. Lehmann.

2 Do we really want to argue about that?

3 A. I'm not arguing.

4 Q. The most important thing is what we have on the screen  
5 right now. Wouldn't you agree from a patient safety  
6 standpoint?

03:18PM

7 A. I have no idea.

8 Q. Okay. Let's see if this will help.

9 This is a description of the problem. There have been  
10 12 reports of migration of the Recovery Filter, part of the  
11 Recovery Filter system for use in the vena cava. Filter  
12 migration has been defined in the literature and for purposes  
13 of this HHE as movement of the filter of greater than two  
14 centimeters.

03:18PM

15 Do you see that?

03:19PM

16 A. Yes.

17 Q. And that's from the site of deployment, correct?

18 A. Yes.

19 Q. Can we give -- a lot of times we make assumptions. I  
20 didn't know what a centimeter was until not that long ago. So  
21 two centimeters, what is that like almost an inch?  
22 Eight-tenths, three-quarters of an inch?

03:19PM

23 A. 2.5 is an inch.

24 Q. So 2.5 is an inch. So two centimeters is 80 percent, if I  
25 did it right. Is that right? Yeah. It's almost

03:19PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 three-quarters, a little more than three-quarters of an inch.

2 Right?

3 A. Yes.

4 Q. A further important distinction in the definition of  
5 migration is whether the filter alone has moved or has moved as  
6 a component of a thromboembolus.

03:19PM

7 Do you see that, sir?

8 A. Yes.

9 Q. In other words, there's an issue whether or not the filter  
10 is just sitting in the vena cava moved or whether it moved  
11 after it got challenged by the kind of clot that it's supposed  
12 to stop, just like what happened in Dr. Asch's study. Yes?

03:20PM

13 A. I don't know. Yes. It says what it says.

14 Q. In the first case a hazard is created by the unintended  
15 movement of the filter, in other words, the filter is just  
16 sitting there and for no apparent reason the filter dislodges  
17 and moves. Right?

03:20PM

18 A. Yes.

19 Q. In the second case, the malfunction is best understood as a  
20 limitation of the ability of the device to carry out its  
21 intended function. These limitations are spelled out in the  
22 literature and in the IFU.

03:20PM

23 Did I read that correctly?

24 A. Yes.

25 Q. In other words, what it's saying is that some of these

03:20PM

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1 migrations happened when the device, which was intended to stop  
2 a clot, actually didn't stop the clot it actually dislodged the  
3 filter. Right?

4 A. Yes.

5 Q. That sounds like it might be a design issue. True?

03:21PM

6 A. No.

7 Q. You actually redesigned the Recovery Filter to be the G2 to  
8 minimize that risk, didn't you?

9 A. To lessen it, yes.

10 Q. I think you would call that a redesign. If you changed the  
11 filter to take care of a problem and you redesigned it to take  
12 care of the problem it was a redesign. True?

03:21PM

13 A. So first of all, it's not a problem. These are  
14 occurrences. And, yes, we always want to make our filter  
15 better. We have total product lifecycle, it's called. We take  
16 all of the information we have talked about today and we put  
17 that into next generation devices. So yes, our desire was to  
18 improve it.

03:21PM

19 Q. Well, sir, what I heard in the beginning of that was this  
20 was not a problem. Is that what you said?

03:21PM

21 A. Yes.

22 Q. So the migration of the Recovery -- your message to this  
23 jury is that the migration issues that were experienced by the  
24 Recovery Filter was not a problem?

25 A. It's not a problem like you say it.

03:22PM

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1 Q. Well, was it a problem to the health and well-being of the  
2 people who experienced those migrations?

3 A. Of course.

4 Q. Was it a problem to the health and well-being of those  
5 people who were seriously injured by those filters when it did  
6 not perform its intended function?

03:22PM

7 A. It's -- yes.

8 Q. Well, there was a big enough problem with what happened  
9 with the Recovery Filter the company put it on hold, didn't it?

10 A. I don't think so, no.

03:22PM

11 Q. You don't remember the company putting it on hold?

12 A. No, but it could have. I don't remember that.

13 Q. And it was a big enough problem in the Asch study where it  
14 migrated four centimeters and the Board, the Ethics Board said  
15 if it happens again we're going to stop the study and Bard said  
16 we're going to look at the redesign. Do you remember that?

03:23PM

17 A. No. That's not true at all.

18 Q. Can we look at Trial Exhibit 559, please. We can take this  
19 one down subject to the redaction issue, Your Honor. I have  
20 already offered this, right? It's in evidence.

03:23PM

21 THE COURT: Folks, that sound is somebody's phone.  
22 Everybody pull your phone out and make sure it's either off or  
23 on airplane mode, please.

24 559 has been admitted.

25 MR. LOPEZ: It is already in?

03:23PM

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1 THE COURT: Yes.

2 MR. LOPEZ: Okay.

3 Could you publish 559, please, to the jury?

4 THE COURT: Yes, you may.

5 BY MR. LOPEZ:

03:24PM

6 Q. Could I see the top section down to the device can be  
7 better understood.

8 Who is George Cavagnaro?

9 A. He was the head of marketing at Bard Peripheral  
10 Technologies.

03:24PM

11 Q. And Doug Uelmen?

12 A. He was in quality at Bard Peripheral Technologies.

13 Q. And we heard from Carol Vierling earlier today. She was  
14 involved in the 510(k) of the Recovery Filter, right?

15 A. Yes.

03:24PM

16 Q. And Mr. Cav -- could you pronounce his name?

17 A. Cavagnaro.

18 Q. Cavagnaro. I felt compelled to report this week's adverse  
19 event, an RNF fracture to the HPB and to our IRB. Did I read  
20 that correctly?

03:25PM

21 A. Yes.

22 Q. Doesn't it say that the IRB suspended the trial effective  
23 immediately until the nature of the problem with the device  
24 could be better understood?

25 A. Yes.

03:25PM

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1 Q. And you don't recall a similar discussion taking place  
2 among you, Dr. Asch, and Dr. Kaufman that if there was one more  
3 migration after the migration happened in Patient 9 that Bard  
4 would stop the study and reevaluate the design of the device?

5 A. Of course I remember that.

03:25PM

6 Q. And that would be a wise thing to do, right? In other  
7 words, if you have one migration and you don't know why it  
8 happened, and you allowed the study to go forward because you  
9 have told all the patients in the study about it and they have  
10 agreed to go forward, if you have another migration that you  
11 ought to stop the study and evaluate the design. Right?

03:25PM

12 A. That's what we agreed to, yes.

13 Q. And but you didn't do that after Recovery was on the  
14 marketplace. You just let migrations happen time after time  
15 after time after time for two years until the G2 was ready for  
16 the marketplace. True?

03:26PM

17 A. No. I would not put it that way.

18 Q. Okay. You had -- did you ever stop selling the Recovery  
19 Filter while it was on the market and having increasing numbers  
20 of migrations until the G2 was ready to be launched on to the  
21 marketplace?

03:26PM

22 A. No.

23 Q. Did Bard tell doctors and patients that they were  
24 experiencing these migrations that were happening out in the  
25 field and that had this happened in the pilot study done in

03:26PM



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1 Canada, that the IRB would have stopped the study and that Bard  
2 would have looked at redesigning the Recovery Filter? Did that  
3 information get shared with doctors?

4 A. No, just the clinical trial information was shared with  
5 doctors.

03:27PM

6 Q. By the way, when Janet Hudnall was out, looks like she went  
7 a lot of different places, Tennessee.

8 A. I don't know where she went.

9 Q. It's on that document.

10 A. That's a list of physicians. That's not necessarily where  
11 she went.

03:27PM

12 Q. Did she take the opportunity when she was on this G2 road  
13 show to tell doctors about this -- these two fractures and the  
14 migration in the first and only patient challenged with a  
15 clinically significant clot in the Asch study?

03:27PM

16 A. I have no idea.

17 Q. Did she take the opportunity to tell doctors that the  
18 ethics board that was monitoring that study stopped the study  
19 as a result of the two fractures in the pregnant woman?

20 A. I have no idea.

03:28PM

21 Q. Did she take the opportunity to tell these doctors that  
22 were using Recovery filters and that she wanted to convert to  
23 the G2 Filter that the reason they thought there was a fracture  
24 in Dr. Asch's study proved to be inaccurate?

25 A. I have no idea what Janet told the doctors.

03:28PM

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1 Q. But Bard knew after its first fracture with a Recovery  
2 Filter and its first fracture with a G2, G2X, and its first  
3 fracture with an Eclipse Filter that it had nothing to do with  
4 the pressures and unique environment of a woman being pregnant.  
5 True?

03:28PM

6 A. I don't know each of those first events. I have no idea.

7 Q. Did Janet Hudnall advise that Dr. Asch told Bard they  
8 shouldn't market the Recovery Filter as a permanent filter  
9 until Bard did a clinical trial?

10 A. Did Dr. Asch tell Janet that?

03:29PM

11 Q. No. I'm sorry. Did Janet tell these doctors that she was  
12 visiting that they ought to -- about Dr. Asch's experience --  
13 I'm sorry. Let me strike that.

14 Did Janet Hudnall tell these doctors that we saw on  
15 that priority list that Dr. Asch thought there should be a long  
16 term clinical trial for this device to be used as a permanent  
17 filter?

03:29PM

18 A. Again, I have no idea what Janet Hudnall told the  
19 physicians.

20 Q. And by the way, speaking of clinical trials, NMT actually  
21 had plans to do a safety clinical trial as was discussed with  
22 Dr. Asch in Europe. Right?

03:29PM

23 A. No. As I spoke of before, it was one of the things we were  
24 considering doing.

25 Q. At NMT there was actually a protocol for a clinical trial

03:30PM

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1 in Europe. True.

2 A. There was a draft. There was never an approved protocol.

3 Q. Well, there were certainly some discussions and plans about  
4 doing a clinical trial. I think we saw it on one of these  
5 exhibits earlier today on the PowerPoint slide from NMT.

03:30PM

6 A. Yes. We were considering it.

7 Q. But when Bard took over NMT there was no discussion, no  
8 consideration, nothing about doing this clinical trial that was  
9 discussed while you were at NMT. True?

10 A. No. I don't recall that.

03:30PM

11 Q. There was no discussion about doing a clinical trial,  
12 right?

13 A. No.

14 Q. At Bard?

15 A. No. I don't know that that's true.

03:30PM

16 Q. Well, could you -- you just don't know?

17 A. That's what I said. I don't know.

18 Q. If there was a discussion about doing a clinical trial,  
19 they kept it from the person who knows more about filters than  
20 anybody else at the company?

03:31PM

21 A. No. It was 16 years ago. I don't remember every  
22 conversation.

23 Q. And you don't remember being asked that question two months  
24 ago?

25 A. No. I don't think we talked about that.

03:31PM

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1 Q. Now, during the -- eventually the G2 was launched, right,  
2 and Bard stopped selling the Recovery Filter?

3 A. Yes.

4 Q. And the G2 was launched as a permanent filter. True?

5 A. Yes, at first.

03:31PM

6 Q. But the Recovery stayed on the market until Bard got  
7 permission from the FDA to start selling the G2 as a permanent  
8 filter. True?

9 A. No. It stayed on the market after G2 was on the market.

10 Some people preferred Recovery.

03:32PM

11 Q. Well, no. You continued to -- well, let me ask you. Do  
12 you have a document, one document, that you can bring to court  
13 where a doctor said, I want you to continue to sell the  
14 Recovery Filter to me even though you are taking it off the  
15 market?

03:32PM

16 A. Yes. We have physicians requesting to keep Recovery.

17 Q. Now, the second question is, could you bring in another  
18 document with you where those doctors were provided with the  
19 health hazard evaluations about the Recovery Filter and  
20 everything that the company knew about the way the Recovery  
21 Filter was causing harm in patients? Can you bring that  
22 document with you to court?

03:32PM

23 A. Of course not. A health hazard evaluation is confidential.

24 Q. Could you bring with you to court any document about a  
25 doctor who said I want to continue using the Recovery Filter

03:32PM

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1 after Bard revealed to the doctor all of its failed migration  
2 resistance testing it did after it was launched?

3 MR. NORTH: Objection, Your Honor. 402 and  
4 argumentative.

5 THE WITNESS: Of course not.

03:33PM

6 THE COURT: Hold on. There's an objection I'm going  
7 to sustain on relevance. I think we need to move on, Mr.  
8 Lopez.

9 MR. LOPEZ: Can I have Trial Exhibit 2248.

10 BY MR. LOPEZ:

03:33PM

11 Q. Just to give -- while that's coming up, to give the jury  
12 some perspective, we're in like the fall of 2005. I can't  
13 remember the exact date, September, October. Is that when the  
14 G2 started to be marketed by Bard?

15 A. Fall is probably as accurate as I can get, yeah.

03:33PM

16 Q. And it was shortly after that, and you are aware of this,  
17 that Bard started to have unexpected reports from physicians  
18 about caudal migration. Do you remember that?

19 A. I do.

20 Q. And it resulted in a health hazard evaluation in February  
21 of 2006, less than six months after the device was on the  
22 market. There was cause for Dr. Ciavarella to do a health  
23 hazard evaluation, correct?

03:33PM

24 A. I don't know.

25 Q. There was some legitimate concern about the G2 Filter and

03:34PM

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1 its caudal migration issues, right?

2 A. I don't know.

3 Q. And did Bard, when they have issues like that, do they do  
4 what's called a DFMEA?

5 A. No. They do that before.

03:34PM

6 Q. Was one performed after the G2 Filter started experiencing  
7 an increasing number of caudal migrations after it was on the  
8 market?

9 A. Yes. That failure mode was added to the DFMEA.

10 Q. Could we have Trial Exhibit 2248 please.

03:34PM

11 Are you familiar with this? We talked about this  
12 document a couple months ago about the DFMEA that was conducted  
13 by Natalie Wong on the G2?

14 A. I don't know if she did the DFMEA, but this report, this  
15 update is by her.

03:35PM

16 Q. Can we go to Page 2248-20.

17 MR. LOPEZ: Your Honor, I'd like to offer 2248 into  
18 evidence.

19 THE COURT: Is there any objection?

20 MR. NORTH: No objection, Your Honor.

03:36PM

21 THE COURT: Admitted.

22 MR. LOPEZ: May I publish to the jury, please, Your  
23 Honor?

24 THE COURT: Yes.

25 BY MR. LOPEZ:

03:36PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. Sir, you have seen this document before, right?

2 A. I have.

3 Q. Explain to the jury what this is.

4 A. It's a table.

5 Q. Okay.

03:36PM

6 A. Of migration, G2 caudal thresholds, and it lists the way  
7 severities are ranked. And you take severity and occurrence

8 and then your ability to detect it and it gives you what's

9 called a quad level. And you see in the bottom right a

10 distribution of those numbers to obtain a certain quad.

03:37PM

11 And so there's a circle, with two Number 3s, which is

12 Quad 3 and a statement that says unacceptable risk per FMEA,

13 Type III above threshold. And then if you read further down to

14 the bottom, because it's a Quad 3, it would require a

15 recommended action prior to product release. But since this

03:37PM

16 occurrence is post-release, this is an update to a previous

17 document, there were no controls in place to be able to detect

18 it prior to launch.

19 Q. Okay.

20 A. So the detection is high and the quad level is high.

03:38PM

21 Q. What we do know from looking at this, based on the data

22 that came in after the G2 was on the market, and based on --

23 this is Bard's process here that they went through, the result

24 was an unacceptable risk Type II -- Type III, I'm sorry, above

25 threshold for caudal migration, true? That's the result?

03:38PM

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1 A. No. That's not the result that's the input.

2 Q. And it said basically what you just said at the end, is  
3 that based on this information, the product shouldn't be  
4 launched?

5 A. No, I didn't say that.

03:38PM

6 Q. What did you say, your exact words?

7 A. I said -- I don't know my exact words. I believe that I  
8 said we observed this issue post-market after the filter was  
9 launched, so we went back and added these occurrences to the  
10 DFMEA that was done prior to launch. And because there was no  
11 control in place because they were unanticipated, we had no way  
12 to reduce the quad level until we developed a test to test it  
13 and then reduce that risk.

03:39PM

14 Q. Device was already on the market, right?

15 A. Yes.

03:39PM

16 Q. And did you -- you know who Natalie Wong is?

17 A. Yes.

18 Q. And you know she was deposed. She gave a deposition in  
19 this case?

20 A. She's been deposed before. I don't know about this case.

03:39PM

21 Q. You know she gave a deposition about this exhibit that  
22 we're talking about?

23 A. I would assume so.

24 Q. And have you read her deposition about what she says about  
25 this document and the results of this document?

03:39PM



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1 A. No. I don't think so.

2 Q. Have you ever talked to her about it?

3 A. No.

4 Q. Were you involved in running this test?

5 A. What test?

03:39PM

6 Q. This FMEA?

7 A. It's not a test.

8 Q. Analysis. The analysis.

9 A. No, I don't think I was.

10 Q. And Type III is what? What's a Type III?

03:40PM

11 A. I don't know.

12 Q. Type III is on the serious end of the scale, right, Type IV  
13 being worse?

14 A. No. I have no idea. Yes, I guess of your severity ranking  
15 column, yes.

03:40PM

16 Q. It's the second highest severity ranking of this analysis,  
17 right?

18 A. Yes.

19 Q. I think you said that based on this, a finding like this it  
20 needed recommended actions prior to product release, which is  
21 kind of silly because the product had already been released,  
22 right?

03:40PM

23 A. It's not silly, it's actually critical. But yes, in this  
24 case it was an update to a document.

25 Q. So if this -- if these results had come in prior to product

03:41PM

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1 release, in other words, just like this, unacceptable risk, all  
2 these numbers, the product would not have been released until  
3 some further action had been taken. True?

4 A. I can't answer that yes or no.

5 Q. Sir, as a result of this caudal migration analysis and the 03:41PM  
6 complaints that were coming in, Bard had to do something,  
7 right, to fix that problem?

8 A. Again, I don't use the word "problem." They were  
9 observations that we did not anticipate.

10 Q. Right. So you don't think a device not staying in place, 03:41PM  
11 going downward and tilting and perforating and potentially  
12 fracturing as a result of that movement is a problem?

13 A. That's not what you asked me, and that's not what this is.

14 Q. I'm asking you a caudal migration, just saying that doesn't  
15 tell the whole story. Caudal migration carries with it some 03:42PM  
16 potentially real serious problems for a patient. True?

17 A. All complications carry serious risk with them as described  
18 in our IFU.

19 Q. Sir, I'm asking about caudal migration right now.

20 A. I'm telling you caudal migration and every complication 03:42PM  
21 have serious risks potentially.

22 Q. Let's talk about caudal migration. That was a unique  
23 problem, serious problem, with the G2 that was not really  
24 experienced to that extent with the Recovery. True?

25 A. I don't use the word "serious." No. That's not true. 03:42PM

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1 Q. Now, if a device has a propensity to move downward it also  
2 has a tendency to tilt, to perforate, and to potentially, when  
3 it tilts, to really lose some efficacy. Isn't that true?

4 A. There's potential for all --

5 Q. I'm talking about migration --

03:43PM

6 THE COURT: You can't talk over each other.

7 MR. LOPEZ: I understand.

8 BY MR. LOPEZ:

9 Q. Right now, sir, I just want you to answer my question.

10 Caudal migration, not all complication with the filters, I'm  
11 talking about the complication that is described in what we  
12 have been describing right now in these documents with the G2  
13 Filter. Caudal migration is not a desirable complication with  
14 any filter. True?

03:43PM

15 A. Yes.

03:43PM

16 Q. And if there are ways to stop that by redesigning the  
17 filter, in the interest of patient safety, a company ought to  
18 do that. Do you agree?

19 A. I don't know they can ever be stopped, but we did try and  
20 improve it.

03:43PM

21 Q. And when a device migrates caudally it means it's not  
22 staying where it was put. It shows some signs of instability.  
23 Would you agree.

24 A. Yes.

25 Q. And prior to the G2 being launched, did Bard ever run any

03:43PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 bench testing to see what the caudal migration results would be  
2 in comparison to, say, the Simon Nitinol Filter or other  
3 filters that were on the market?

4 A. No. I already described that. That's why the quad level  
5 is what it is. There was no test prior to launch.

03:44PM

6 Q. Now, there was a test done after the device stayed on the  
7 market and the company continued to get increasing number of  
8 reports of caudal migration. True?

9 A. Yes. We responsively developed a test.

10 Q. You did a test -- can we bring up Trial Exhibit 1578 --  
11 called the Caudal Push Test, right?

03:44PM

12 A. Yes.

13 Q. And that was done in November of 2006. Correct?

14 A. I believe August, but yes.

15 Q. It says "dates approved" if you look down at the end of  
16 this document.

03:44PM

17 THE COURT: This is not in evidence.

18 MR. LOPEZ: Your Honor, I'd like to offer this in  
19 evidence at this time, Exhibit 1578.

20 MR. NORTH: No objection, Your Honor.

03:45PM

21 THE COURT: Admitted.

22 MR. LOPEZ: Publish to the jury please, Your Honor.

23 THE COURT: You may.

24 BY MR. LOPEZ:

25 Q. Sir, this is approved in November of 2006, right?

03:45PM

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1 A. It's approved in November but it began in August.

2 Q. And this is a test that was designed to see how the G2  
3 Filter would resist whatever pressures were causing it to  
4 caudally migrate, right?

5 A. It was to develop tests.

03:45PM

6 MR. LOPEZ: Can we go to Page 7 of 21 on this  
7 document?

8 BY MR. LOPEZ:

9 Q. This was a caudal migration test of the G2 -- okay. This  
10 was going to be a test that involved more than just the G2. It  
11 was going to involve the Simon Nitinol Filter, the Recovery  
12 Filter, and some of the competitor filters to the G2, correct?

03:46PM

13 A. Yes.

14 Q. And, by the way, are there other filters on the market that  
15 have unlimited retrievability windows in their IFUs?

03:46PM

16 A. I don't know what the select IFU is or the Option 1  
17 currently.

18 Q. But this was a test where Bard was going to see how do they  
19 measure up in caudal migration against a number of other  
20 filters, right?

03:47PM

21 A. So the OptEase and the Tulip did not.

22 Q. So let's go to Page 11 of 21. And this is a graph showing  
23 the results of this caudal migration push test. Do you see  
24 where I am?

25 A. I do.

03:47PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. Okay. Now the graph is hard to read, I understand. But if  
2 you look at the very bottom line, this is the average peak  
3 load. In other words, that's the amount of load to make the  
4 device move downward, right?

5 A. Yes.

03:47PM

6 Q. And the device that has the -- took the minimum amount of  
7 load to move downward was what?

8 A. The Greenfield.

9 Q. And then the next one is the G2, right?

10 A. Yes.

03:48PM

11 Q. In fact, the G2 was worse than the Recovery Filter in this  
12 test, wasn't it?

13 A. Yes.

14 Q. And it was worse than the Tulip by a long shot if you look  
15 at this graph, right?

03:48PM

16 A. It was worse.

17 Q. And the Simon Nitinol Filter, which was the predicate  
18 device to the Recovery Filter, was -- the G2 was also much  
19 worse than the Simon Nitinol Filter for caudal migration,  
20 right?

03:48PM

21 A. Yes.

22 Q. Same with O for OptEase, a competitor, the retrievable  
23 competitor of Bard's. True?

24 A. Yes.

25 Q. Now, let's go to Page 21 of 21, please.

03:48PM

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1 By the way, while this test was going on, while the  
2 test was being developed, and during the time Bard was  
3 continuing to receive complaints of fracture, migration,  
4 perforation, and tilt, Bard continued to -- they didn't put a  
5 hold on this. They continued to market this device, right, the 03:49PM  
6 G2?

7 A. Yes.

8 Q. In fact, it was only a permanent device at the time, but  
9 Bard wanted to make it a retrievable device so it launched a  
10 retrievability study called the EVEREST study, right? 03:49PM

11 A. That's correct.

12 Q. And the conclusion here you will see of this test, this  
13 caudal push test, the push test was the most successful test  
14 method and should be used as the primary test method for  
15 evaluating the caudal migration resistance of filters in the 03:49PM  
16 future. The radial compression test can be used as a secondary  
17 evaluation method to further understand filter behavior under  
18 different IVC loading conditions and should be used for  
19 informational purposes only. The rolling test has limited  
20 applicability and should not be continued to be used for 03:50PM  
21 evaluation of caudal migration resistance.

22 So it determined that this was the best test at the  
23 time to measure differences in caudal migration among various  
24 devices. Right?

25 A. Yes. 03:50PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. And it's clear that when you look at not just the graph but  
2 the numbers, in fact, can we look at 12 of 21, please. If you  
3 just look at the pure numbers, the differences are dramatic.  
4 Would you agree?

5 A. I can't see it. I'm sorry.

03:50PM

6 Q. See the G2, the mean, 23.83; the Tulip, 216.24; the Simon  
7 Nitinol Filter, 251.55; and the OptEase 309.23. That shows a  
8 significant difference in the ability of a G2 to resist caudal  
9 migration, doesn't it?

10 A. It does.

03:51PM

11 Q. And Bard continued to sell the G2 and made no changes to  
12 deal with caudal migration until the device that Bard made  
13 after Doris Jones' device. Right?

14 A. We did a lot of work. We did not commercialize the device  
15 until then, yes.

03:51PM

16 Q. So we're in 2006 where a test reveals what we have just  
17 talked about. We have a FMEA in March of 2006 where the result  
18 was unacceptable risk. You testified earlier that you were  
19 starting to receive reports of caudal migration that you  
20 weren't expecting. And Bard continued to sell a device,  
21 including the Eclipse, that did not fix its caudal migration  
22 problem. True?

03:52PM

23 A. Again, I don't say we have a caudal migration problem. It  
24 did not improve caudal migration resistance.

25 Q. It continued to have the propensity to caudally migrate at

03:52PM



—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 rates significantly higher than even the Recovery Filter and  
2 the Simon Nitinol Filter. True?

3 A. It did, yes.

4 Q. In fact, I think I saw a document that from the standpoint  
5 of caudal migration it was 610 times more likely to caudally  
6 migrate than the Recovery Filter. Do you remember seeing that?

03:52PM

7 A. No.

8 Q. Now, after this test, the information that was coming in  
9 from the field, the FMEA of unacceptable risk, did that  
10 information together get distributed to physicians so that they  
11 could know what was going on within Bard with respect to the  
12 caudal migration of the G2?

03:53PM

13 A. No. They were not aware of our testing.

14 Q. And then when Bard went back to FDA for another 510(k)  
15 application for the hook on the G2X, it had to go through the  
16 same process as preparing, testing, and paperwork and  
17 submitting to FDA and for FDA to clear it before you could even  
18 sell it with a hook on it, right?

03:53PM

19 A. Of course.

20 Q. And you didn't take that opportunity while you had the  
21 FDA's attention to tell them that you had already determined  
22 that the G2 needed caudal hooks put on it to solve the caudal  
23 migration problem, did you?

03:53PM

24 A. Actually, I think we did.

25 Q. But you didn't make that change, did you?

03:54PM

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1 A. We did make that change.

2 Q. You didn't make that change before Doris Jones got her  
3 Eclipse device, right?

4 A. That's true.

5 MR. LOPEZ: Could I have 4409, please, Trial Exhibit  
6 4409.

03:54PM

7 BY MR. LOPEZ:

8 Q. You are familiar with this document, of course?

9 A. Yes. We talked about it earlier.

10 MR. LOPEZ: I'm going to offer this, 4409, into  
11 evidence, Your Honor.

03:55PM

12 MR. NORTH: No objection, Your Honor.

13 THE COURT: Admitted.

14 MR. LOPEZ: Publish to the jury, please.

15 THE COURT: You may.

03:55PM

16 BY MR. LOPEZ:

17 Q. Sir, what is this document?

18 A. It's a brochure for the G2 Filter system for permanent  
19 placement.

20 Q. Did the information contained on this document ever change  
21 throughout the course of the time that the G2 was being  
22 marketed by Bard?

03:55PM

23 A. I don't know.

24 Q. And could we go to the next page, please? And could we  
25 look at the section there on the right, the section above the

03:55PM

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1 bullet points. I'm not sure the jury -- there we go.

2 Okay. This is Bard's marketing brochure, and this is  
3 the information that Bard approved, corporately approved to be  
4 the messaging that went out in the medical industry about its  
5 G2 Filter, correct?

03:56PM

6 A. Yes.

7 Q. It says the G2 Filter combines the best design features of  
8 Bard's existing vena cava filters. The existing vena cava  
9 filters that existed at that time at Bard would have been the  
10 Simon Nitinol Filter. Correct?

03:56PM

11 A. Yes. That's one.

12 Q. And the Recovery Filter, at least for a little while  
13 longer. Right?

14 A. Yes.

15 Q. And to create a brand new permanent filter platform taking  
16 strength and stability to a new level. Did I read that  
17 correctly?

03:56PM

18 A. You did.

19 Q. And strength again is it won't break?

20 A. Partially.

03:56PM

21 Q. And stability means it's going to stay where you put it?

22 A. Right.

23 Q. And meaning when you say a device is stable and you say you  
24 have taken it to a whole new level, or to a new level, you are  
25 actually saying it's better than the devices you have on the

03:57PM

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1 market -- I'm sorry -- it's better than the predecessor devices  
2 that are described here?

3 A. No. That's not what this says.

4 Q. Well, what's "to a new level"? It means better, doesn't  
5 it?

03:57PM

6 A. Better than Recovery.

7 Q. It says existing vena cava filters, doesn't it?

8 A. It says we took the design features of existing vena cava  
9 filters.

10 Q. And this is a permanent filter and the only other permanent  
11 filter that Bard was selling at the time was the Simon Nitinol  
12 Filter, right?

03:57PM

13 A. No. The Recovery was also a permanent filter.

14 Q. But the Recovery -- but again, this language after Recovery  
15 was off the market stayed in this brochure?

03:57PM

16 A. That's my understanding, yes.

17 Q. And as this brochure was on the market after the Recovery  
18 Filter was on the market, taken off the market, the only  
19 existing vena cava filter would have been the Simon Nitinol  
20 Filter. True?

03:58PM

21 A. Yes, but that doesn't mean we didn't take the best design  
22 features of both of them.

23 Q. I'm just reading what's on the document, sir.

24 And let's go down to the bullet points, please. Let's  
25 go to Trial Exhibit 1616, please. Let's try Trial Exhibit

03:58PM

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1 4438. Might be a better copy of the brochure.

2 Okay. This is the G2 Express. What is the G2  
3 Express?

4 A. It is the next generation filter from the G2.

5 Q. And I have always been confused. Sometimes I see G2X and I 03:59PM  
6 see G2 Express. Are they the same?

7 A. They are.

8 Q. Let's go to the next page. So this would have been the  
9 predecessor device to the Eclipse, correct?

10 A. Yes. 03:59PM

11 Q. And nothing was done to the G2 Express or the G2X to deal  
12 with its tilting or its caudal migration or perforation issues.  
13 True?

14 A. It didn't have tilting or caudal migration issues.

15 Q. Sir, I just asked you if it -- did it do anything -- let's 04:00PM  
16 put it -- let me ask it this way.

17 Was there anything done to the design of the G2X to  
18 help improve its performance from the standpoint of migration,  
19 perforation, fracture, or tilt?

20 A. Not until Meridian was launched. 04:00PM

21 Sorry. That's not true. Sorry. Excuse me. I said  
22 that incorrectly.

23 MR. LOPEZ: Your Honor, I'd like to move 4438 into  
24 evidence, please.

25 MR. NORTH: No objection, Your Honor. 04:00PM

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1 THE COURT: Admitted.

2 MR. LOPEZ: And published to the jury, please.

3 THE COURT: Yes.

4 MR. LOPEZ: Can we go to the next page? That might be  
5 the last page of this one, right?

04:00PM

6 Let's go to 4409. I'm sorry 1616, the patient  
7 brochure.

8 THE COURT: Are you saying 1616?

9 MR. LOPEZ: 1616. 1616.

10 BY MR. LOPEZ:

04:01PM

11 Q. Mr. Carr, in addition to providing brochures that  
12 salespeople would give to doctors and have at hospitals and  
13 places like that, they also developed brochures or pamphlets or  
14 something to give the patients, right?

15 A. Sometimes.

04:01PM

16 Q. And this was one of those things, one of those items. A  
17 Patient Questions and Answers, right?

18 A. It appears to be.

19 Q. And the intent was to -- this was Bard's official messaging  
20 that it wanted to give to patients. Right?

04:02PM

21 A. It's a Q & A; no more, no less.

22 Q. I understand. In other words, if Bard wanted patients to  
23 have information directly from Bard, it would be contained in  
24 this Patient Questions and Answers. Right?

25 A. I'm sure not all information is contained in there. It is

04:02PM

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1 a selection of questions answers.

2 Q. Right, the questions and answers of the information that  
3 Bard thought was the most important information, at least from  
4 Bard, that the patient ought to have about its G2 Filter.

5 Right?

04:02PM

6 A. I have no idea about importance.

7 Q. How do these -- these are corporately approved, aren't  
8 they, before they are given to doctors to give to patients?

9 A. Sure.

10 Q. And there was also a patient brochure -- we don't have time  
11 to go through this, and we won't. But I just want to confirm  
12 that this brochure, this Q & A was intended to be handed to  
13 doctors and it was written by -- I mean handed to patients, and  
14 it was written by Bard?

04:03PM

15 A. I don't think it was handed to patients, no. It was more  
16 left in a lobby like you would see in your dentist office or  
17 something.

04:03PM

18 MR. LOPEZ: Did I move 1616, Your Honor? I'd like to  
19 move it into evidence at this time.

20 THE COURT: Any objection?

04:03PM

21 MR. NORTH: No objection, Your Honor.

22 THE COURT: Admitted.

23 MR. LOPEZ: Can we publish it to the jury, Your Honor?

24 THE COURT: You may.

25 MR. LOPEZ: If we just look at maybe the first page.

04:04PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 And then the next page. And the next page.

2 BY MR. LOPEZ:

3 Q. So, sir, this Q&A has to be a fair balance, too, doesn't  
4 it? Anything that deals with marketing or sales has to be  
5 fairly balanced. Right?

04:04PM

6 A. I believe so.

7 Q. It can't be false and misleading, right?

8 A. No.

9 Q. I mean, I'm right, right? It cannot be false and  
10 misleading?

04:04PM

11 A. Yes, it cannot.

12 Q. Trial Exhibit 4430. Ask you if you recognize this  
13 document. This is the Eclipse brochure?

14 A. It could be. I'd like to see the approval page.

15 Q. Says "final" on the top. Do you see that?

04:05PM

16 A. Yes.

17 MR. LOPEZ: I'd like to move 4430 into evidence, Your  
18 Honor.

19 MR. NORTH: No objection, Your Honor.

20 THE COURT: Admitted.

04:05PM

21 MR. LOPEZ: Thank you, Your Honor.

22 Publish 4430, please.

23 THE COURT: Yes.

24 BY MR. LOPEZ:

25 Q. Now, if this device -- physically as you look, the jury saw

04:05PM



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1 this, I think, yesterday it got passed around. If you were to  
2 put this next to a G2X it would look exactly the same except  
3 this one has kind of a blue tint to it. Right?

4 A. Very similar.

5 Q. From the standpoint of the arms and the legs and the hooks  
6 it's the same as the G2 and G2X?

7 A. It is very similar.

8 MR. LOPEZ: Can we go to the next page, Gay, please.

9 BY MR. LOPEZ:

10 Q. And this device was meant for doctors?

11 A. I'm sorry?

12 Q. I'm sorry. This brochure was meant to be given to doctors  
13 by the sales force?

14 A. Yes, it could be.

15 Q. And could we go to trial Exhibit 4433, please.

16 Can you describe what's 4433?

17 A. It appears to be a Q&A pamphlet just like -- similar to the  
18 one we saw for G2.

19 Q. This is specific to the Eclipse, right?

20 A. Yes.

21 Q. And this is the -- and this is, again, produced by Bard.  
22 Right?

23 A. Yes.

24 Q. Everything that is contained in here is the messaging that  
25 Bard wants to put in this patient brochure, correct?

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 A. I don't see the approval page, so I don't know for sure.

2 But if that's the case, then yes.

3 MR. LOPEZ: I'd like to offer 4433 into evidence at  
4 this time, Your Honor.

5 MR. NORTH: No objection, Your Honor.

04:07PM

6 THE COURT: Admitted.

7 MR. LOPEZ: May I publish it to the jury?

8 THE COURT: You may.

9 BY MR. LOPEZ:

10 Q. This has a little red stamp, "final" on it?

04:07PM

11 A. Yes, it does.

12 Q. And this actually gets folded up into like a brochure,  
13 right?

14 A. I believe so, yes.

15 Q. And I think you told us you see these in medical offices  
16 now where they have pamphlets and stuff that patients walk in  
17 and take one of these and read them, right?

04:08PM

18 A. They can.

19 MR. LOPEZ: 770, please.

20 BY MR. LOPEZ:

04:08PM

21 Q. Sir, can you see Exhibit 770? Are you familiar with this  
22 document?

23 A. I have probably seen it before in my deposition. I'm  
24 fairly familiar.

25 Q. And what is a Concept POA?

04:09PM

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1 A. So it's a business document that describes different  
2 strategic rationales, business cases to should we do a project  
3 and what claims we would hope to get out of it; some market  
4 information; and it's really just a product opportunity  
5 assessment.

04:09PM

6 Q. And we haven't seen the word "Denali" before. What is  
7 Denali?

8 A. Denali is our current vena cava filter.

9 Q. If we go to -- is there any way for you to give me a date  
10 of this document?

04:10PM

11 A. Are you asking me?

12 Q. Yeah. Is there any way to date this?

13 A. I don't think so.

14 Q. If you look at the very first page -- I'm sorry. Do you  
15 see it -- well, let's look at --

04:11PM

16 MR. LOPEZ: Can I move this into evidence, Your Honor?  
17 I'd like to move this into evidence at this time.

18 MR. NORTH: No objection, Your Honor.

19 THE COURT: Admitted.

20 MR. LOPEZ: If I could publish it to the jury, please.

04:11PM

21 THE COURT: You may.

22 BY MR. LOPEZ:

23 Q. If you look at the very bottom of the first page that  
24 reads: In order for this project to have impact described in  
25 this POA, the filter must have no cephalad migrations unless

04:12PM

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1 caudal migrations have been reported for G2X.

2 Do you see that, sir?

3 A. I do.

4 Q. The filter must have improved fracture rates comparable, if  
5 not better, tilt performance and penetration rates and continue  
6 to provide long term retrievability.

04:12PM

7 Do you see that, sir?

8 A. I do.

9 Q. And while this doesn't give us a date, it does tell us that  
10 while the G2X is the Bard filter that is being marketed. Would  
11 you agree with me?

04:12PM

12 A. No.

13 Q. If you look at the strategic rational value to Bard  
14 Peripheral Vascular on the first page: There is a heightened  
15 sensitivity to complications with IVC filters in the market.  
16 Often all the filter business in one account is lost or  
17 significantly threatened as a result of a difficult retrieval  
18 case or a complication. Improving upon the performance of the  
19 G2 and G2X filters will not only help protect current business  
20 but will re-energize the sales force to capture more share and  
21 help Bard take initiative in the marketplace.

04:13PM

22 Did I read that correctly?

23 A. You did.

24 Q. Does that help now convince you that this is during the G2  
25 and G2X era at Bard?

04:13PM

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1 A. It could be.

2 Q. Let's go to the next page. They are describing here, they  
3 say: The Denali Filter and it's accompanying deployment system  
4 should deliver the following. Do you see that?

5 A. Yes.

04:14PM

6 Q. And under migration, the filter should have improved caudal  
7 migration resistance and similar improved cephalad migration  
8 resistance compared to G2. Correct?

9 A. Yes.

10 Q. Is it true this is talking about the next generation of  
11 device that Bard is planning to design and market?

04:14PM

12 A. No.

13 Q. This isn't talking about the next generation beyond G2 and  
14 G2X?

15 A. No, because it also talks about Eclipse.

04:14PM

16 Q. Where is that?

17 A. The bottom row of that same table.

18 Q. The Denali deployment system color should visually  
19 differentiate the system from Eclipse and G2 filters?

20 A. Correct.

04:15PM

21 Q. Now we know the G2, the G2X, and Eclipse is on the market,  
22 right?

23 A. No, I don't know that they are all on the market.

24 Q. They are talking about improvement of the Eclipse and G2X  
25 filters?

04:15PM

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1 A. But there's history. They may or may not be on the market.

2 Q. Well, whatever device is on the market, we can determine  
3 that with another witness or by this document by looking at it  
4 later. Whatever device is on the market, and whatever time  
5 period this is, Bard is talking about a filter that should have  
6 improved caudal migration resistance and similar or improved  
7 cephalad migration resistance compared to G2, correct? It's  
8 right there under migration.

04:15PM

9 A. Absolutely.

10 Q. And as far as tilt, the next filter should have improved  
11 tilt performance in comparison to the G2, correct?

04:16PM

12 A. Yes.

13 Q. And the filter should have improved fracture performance in  
14 comparison to the G2, right?

15 A. Yes.

04:16PM

16 Q. And the filter should deliver improved penetration  
17 performance in comparison to the G2, correct?

18 A. Yes.

19 Q. And then these are issues that existed in the G2, all of  
20 these things that required improvement existed in the G2 in  
21 2006. Right?

04:16PM

22 A. They are not issues that were in the G2. They are  
23 observations. And this product opportunity assessment, which  
24 is a business document, wants each of those conditions to be  
25 met and why wouldn't you.

04:16PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 Q. Okay. Because improving upon the performance, if you look  
2 at Page 1 again, of the G2 and G2X filters, will not only help  
3 protect current business but will re-energize the sales force.  
4 Right?

5 A. Yes.

04:17PM

6 Q. Was the sales force in need of being re-energized?

7 A. Absolutely.

8 Q. So like the Recovery Filter, Bard learned from the clinical  
9 experience in the G2 after it was put on the market, right?

10 A. We always learn from our clinical experience all the time,  
11 yes.

04:18PM

12 Q. Well, basically, they didn't know much about its -- it had  
13 no clinical experience with the G2 before it launched, right?

14 A. That's true.

15 Q. And so what they did is they put it out there not knowing  
16 really how it was going to work in a human being and waited  
17 until it started getting reports of what might be wrong with  
18 the product that might require you to have to improve it?

04:18PM

19 A. Absolutely not.

20 Q. Well, how else could it be? You make a device, you test it  
21 in a laboratory, you don't put it in a human being before it's  
22 launched. True?

04:18PM

23 A. Correct.

24 Q. And your concept of determining whether or not it's safe is  
25 not to do a controlled monitored clinical trial where a doctor

04:19PM

—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3-Carr-Direct—

1 is paying attention to the patient, having the patient come  
2 back in to see if the device is actually performing in the  
3 manner in which it performed in a sheep or in the laboratory,  
4 Bard's idea was to put it out in the open marketplace without  
5 any monitoring requirements or recommendations and wait for  
6 doctors who may or may not be reporting problems with the  
7 device. Is there anything inaccurate about that, sir?

04:19PM

8 A. Yes.

9 THE COURT: Go ahead and finish your answer.

10 THE WITNESS: Yes. We did all the appropriate testing  
11 to put that device on the market. We did all of the benchtop  
12 testing necessary to show that it was dramatic improvement to  
13 the Recovery Filter in the design criteria that we were aiming  
14 to improve, and we did that. And we submitted a 510(k) to the  
15 FDA, and they concurred that we did all the proper testing.

04:19PM

04:20PM

16 THE COURT: All right. We need to break at this  
17 point. I have got a 4:30 hearing. So we're going to break  
18 until tomorrow morning, Ladies and Gentlemen. We will plan on  
19 seeing you at 9:00. Please remember not to do any research or  
20 talk about the case. And we'll see you then.

04:20PM

21 (Jury out at 4:20 p.m.)

22 THE COURT: Counsel as of the end of today, plaintiff  
23 has used 11 hours and 10 minutes and defense, two hours and 53  
24 minutes.

25 I want to ask a couple of questions of plaintiffs'

04:21PM



—5-17-18-CV 15-2641-Jones v Bard-Jury Trial-Day 3—

1 counsel about the documents we discussed this morning. I  
2 assume that's you, Mr. Combs.

3 MR. O'CONNOR: The summary?

4 THE COURT: Well, all three of the categories of  
5 documents.

04:21PM

6 My first question is: Tell me how it is you intend to  
7 use these documents. What's the point you are going to be  
8 making with the summary, with monthly reports, with the  
9 complaint files?

10 MR. O'CONNOR: Well, to establish notice, to show the  
11 defect, the design defect, to rebut the defense claim.

04:21PM

12 THE COURT: I didn't ask my question clearly enough.  
13 What are you going to do with them in front of the  
14 jury?

15 MR. O'CONNOR: In front of the jury?

04:22PM

16 THE COURT: Yeah.

17 MR. O'CONNOR: We're going to use them to show those  
18 issues.

19 THE COURT: How. What are you going to do?

20 MR. O'CONNOR: Use them with witnesses, for example.

04:22PM

21 THE COURT: Give me an example. Let's say you have  
22 got the 1006 chart in front of you. I'm trying to understand  
23 how you intend to use the evidence so I can do the 403  
24 balancing.

25 MR. O'CONNOR: So for example, to cross-examine their

04:22PM

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1 witnesses on what they knew and about the complaints; that they  
2 were receiving complaints; to dispel this notion that a  
3 fracture in a pulmonary artery is not serious; that they had  
4 complaints about it; that they were aware these would fracture  
5 and migrate and go to places like the pulmonary artery which 04:22PM  
6 means they have to go through the heart; to show this danger of  
7 complication to overcome this contention that was given to this  
8 jury that this is not a serious injury.

9 THE COURT: Any other uses you intend to make of it?

10 MR. COMBS: Your Honor, a primary defense in this 04:23PM  
11 case, maybe the primary defense, is that Bard filters, they  
12 pass risk/benefit analysis because they have exceptionally low  
13 rates of complications. A chart of complications goes to both  
14 the quantity and the severity as direct relevance to the  
15 risk/benefit analysis. So I don't think there's any -- 04:23PM  
16 certainly no unfair prejudice that could substantially outweigh  
17 that direct relevance to the defense in this case.

18 THE COURT: Let me explain why I'm asking. There are  
19 cases which have held when you are using other instances of  
20 failure in a product, if it's going to notice you can take a 04:23PM  
21 sampling. One case said four out of 32, show those to the  
22 jury. But if you put all 32 in, it's going to give it undue  
23 weight and it will violate 403. Where the argument could be if  
24 it's going to show a product defect you could make that  
25 illustration with a subset rather than all of them. 04:24PM

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1 I'm trying to evaluate those cases in how this  
2 evidence will be used. So I'm interested -- I don't know if  
3 you can address that specific kind of thing.

4 MR. COMBS: Your Honor, they have made all the filters  
5 and all the complications an issue multiple times in opening 04:24PM  
6 and certainly going to repeat that with multiple witnesses  
7 about their extremely low failure rates. All these failures  
8 and their severity go to rebut that, not just a sample to give  
9 some examples.

10 THE COURT: Well, hold on Mr. O'Connor. 04:24PM

11 Are you going to have -- are you going to use them  
12 statistically or are you going to count up the number of  
13 failures that you have in your 1006 and say this is the failure  
14 rate, for example?

15 MR. COMBS: I think the answer is all the above, Your 04:25PM  
16 Honor. I mean, we don't know exactly what they are going to  
17 say on direct and what we need to cross-examine them with. I  
18 think those are all possibilities, Your Honor.

19 MR. LOPEZ: Your Honor, could I say one thing?

20 THE COURT: One thing. 04:25PM

21 MR. LOPEZ: IFU is obviously a big defense. He  
22 displayed that in opening. And it has certain things in there  
23 about -- that describe really what happened to our client in  
24 some ways. They are certainly going to argue that. They are  
25 going to say what's the beef? 04:25PM

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1           What we have in these files is something that you  
2       won't see in the Simon Nitinol file. And you won't see in  
3       other -- we have the MAUDE database. In other words, it's our  
4       ability to show I think Mr. Comb said it, not just the type of  
5       incident but its severity and its frequency are extremely  
6       important. See, their defense is what's the big deal? We have  
7       migration in the IFU. We have --

04:25PM

8           THE COURT: I know what their defense is. I'm just  
9       trying to drill in on exactly what you intend to use it for.

10          MR. LOPEZ: I think there's something pretty unique  
11       and different about the Bard filters that are not part of the  
12       way they should be described in the IFU or to doctors. In  
13       other words, it's not just migration. Some of these things  
14       have, and you heard in the Booker trial and we saw in the  
15       EVEREST results, where because of caudal migration you get  
16       fracture, tilt, and perforation sometimes. There's this  
17       cascade. There's nothing in the literature that describes  
18       this. This is a unique problem with the G2 and G2X as seen in  
19       their own study. There's that chart that shows those diagrams.  
20       So unless you have the details of all that you can't develop  
21       that part of why this is not an SIR guideline case. It just  
22       talks about the fracture rate or the perforation rate. It's  
23       got its own unique problem that would reveal itself in its  
24       clinical trial. And we -- not only was it in the clinical  
25       trial --

04:26PM

04:26PM

04:26PM

04:27PM

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1 THE COURT: I have got about one minute before my  
2 hearing starts.

3 MR. LOPEZ: I'm saying there's a bunch of those in  
4 here. We've got to be able to show this is a prolific issue.  
5 It's not just caudal migration or just not fracture. This is  
6 cascade.

04:27PM

7 THE COURT: Mr. North, you wanted to say something on  
8 this?

9 MR. NORTH: I know Your Honor has to go. I just  
10 wanted to say that for the purposes they have just articulated,  
11 you know, we have never said they cannot or should not be able  
12 to put the number of events in. They could talk about the type  
13 of severity of these events that do occur. They can ask  
14 witnesses about that. And maybe consistent with the case we  
15 showed the Court, the *Newcastle* case, they could show a  
16 sampling of some of these.

04:27PM

04:27PM

17 But to pile on hundreds of hundreds of hundreds of  
18 these events like they are going to, I think, triggers the 403  
19 balance.

20 THE COURT: Last question. Can I see the 1006 exhibit  
21 you are intending to use so I can actually look at it?

04:28PM

22 MR. O'CONNOR: We'll get it to you.

23 THE COURT: I do have -- so this is the document.

24 MR. O'CONNOR: We have different versions we're using  
25 today. This is the complete document.

04:28PM

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1 THE COURT: I want to know what you want to put into  
2 evidence because I'm going to look through it and ask how much  
3 of this is cumulative, how much of this is prejudicial so I can  
4 do the 403 balance.

5 MS. SMITH: This is the one with all of them.

04:28PM

6 MR. O'CONNOR: They are copied on both sides.

7 THE COURT: So is this just Bard filter -- well, is  
8 this the Recovery, G2, G2X, and Eclipse?

9 MS. SMITH: Correct.

10 THE COURT: And the four complications.

04:29PM

11 MS. SMITH: Correct.

12 THE COURT: So that's what you are wanting to put into  
13 evidence.

14 MR. O'CONNOR: Yes, sir.

15 THE COURT: The other question I had for plaintiff  
16 is -- by the way, what's the number of this?

04:29PM

17 MS. SMITH: It's written on there, I believe 4565.

18 THE COURT: The other question for plaintiff is, Mr.  
19 North made an objection this morning that the monthly reports  
20 that went to management had lots of other stuff in them besides  
21 this information which was irrelevant and prejudicial. What is  
22 plaintiffs' response on that?

04:29PM

23 MR. LOPEZ: You mean that talks about the stents and  
24 stuff? We can take that out.

25 THE COURT: I don't know what it means. I assume you

04:29PM

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1 have talked and you know what they are objecting to in the  
2 monthly reports.

3 MS. REED-ZAIC: At the end of the monthly reports the  
4 Bard filters are the very first section of the attachments in  
5 the monthly reports and then it continues with different Bard  
6 filters. Those can be removed.

04:30PM

7 THE COURT: Is that addressing your concern about the  
8 monthly reports, Mr. North? I know you have got the other  
9 objections.

10 MR. NORTH: Yeah. It should, Your Honor. I would  
11 need to look back at them real quickly in light of what she  
12 just said.

04:30PM

13 THE COURT: Am I correct that there would be nothing  
14 then in the monthly reports that wouldn't also be included in  
15 the summary in terms of filters and events?

04:30PM

16 MR. NORTH: No. The last three pages have the same  
17 summaries that are in 1006.

18 THE COURT: That's what I'm asking.

19 MR. NORTH: Yeah. Each monthly report has that  
20 month's incidence.

04:30PM

21 THE COURT: And my understanding is the plaintiff is  
22 not intending to put into evidence the actual complaint file  
23 such as those you used, Mr. O'Connor, to show where the  
24 information came from. Is that right?

25 MR. O'CONNOR: That's the reason we did the summary.

04:30PM

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1 That's correct.

2 THE COURT: You moved two of them in today, but you  
3 are not intending to move all of the others in?

4 MR. O'CONNOR: No, because we believe the summary can  
5 substitute.

04:30PM

6 MS. REED-ZAIC: Your Honor, if I could clarify, I  
7 don't believe the global monthly report contains every single  
8 complaint for that month. It seems there are select few.

9 THE COURT: All right. I think I understand that.

10 Thank you all. See you at 8:30.

04:31PM

11 (Proceeding concluded at 4:31 p.m.)

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C E R T I F I C A T E

I, LAURIE A. ADAMS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 18th day of May, 2018.

s/Laurie A. Adams

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Laurie A. Adams, RMR, CRR